No. 23-10640

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRADLEY SANDERS, *et al.*,

Plaintiffs-Appellants,

v.

AJANTA PHARMA USA, INC., *et al.*,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

BRIEF OF RETAILER AND DISTRIBUTOR DEFENDANTS-APPELLEES

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Defendant-Appellee Cardinal Health, Inc. and counsel for Defendants-Appellees Albertsons Companies, Inc., Amazon.com, Inc., BJ's Wholesale Club Holdings, Inc., Costco Wholesale Corporation, CVS Pharmacy, Inc., Duane Reade, Inc., Giant Eagle, Inc., H-E-B Grocery Company, LP, Publix Super Markets, Inc., Safeway Inc., ShopRite Supermarkets, Inc., Southeastern Grocers, Inc., Target Corporation, Walgreen Co., Walgreens Boots Alliance, Inc., Wakefern Food Corporation, Winn-Dixie Stores, Inc., and The Vons Companies, Inc., on behalf of the Retailer and Distributor Defendants identified in the Addendum attached hereto, certifies that the previously filed Certificate, *see Krause*, CA11 Appeal No. 23-13283, Dkt.101, remains correct, other than:

- AmerisourceBergen Corporation (**ABC**) has changed its name and stock ticker to Cencora, Inc. (**COR**).
- BlackRock, Inc. no longer owns 10% or more of the stock of BJ's Wholesale Club Holdings, Inc.

Dated: July 25, 2024

Respectfully Submitted,

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STATEMENT REGARDING ORAL ARGUMENT

The Retailers and Distributors request oral argument because oral argument will aid in the Court's resolution of the multiple issues raised by the numerous consolidated appeals in which the Retailers and Distributors file this brief (Nos. 21-12618, 21-14325, 23-10640, 23-11080, 23-13182, and 23-13283)—which, as Plaintiffs note, involve "many thousands of cases." Omnibus Br. at i.[*]

[*] This brief refers to the 27,970-word consolidated brief that Plaintiffs filed in each of the consolidated appeals as "Omnibus Br." This brief refers to the additional brief that Plaintiffs filed as to the appellants with Rule 58 judgments in appeal No. 21-12618 as "Generics-Only Br." Consistent with Eleventh Circuit Local Rule 28-5, this brief cites to all record documents, other than transcripts, using the document's internal pagination.

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STATEMENT REGARDING ADOPTION OF BRIEFS OF OTHER PARTIES

The Retailers and Distributors adopt by reference the brief of the Brand Defendants-Appellees (filed July 25, 2024). Fed. R. App. P. 28(i); 11th Cir. R. 28-1(f). Specifically, the Retailers and Distributors adopt Brand Defendants-Appellees' Argument Section II: The District Court Did Not Abuse Its Discretion in Excluding Plaintiffs' General-Causation Experts. *Id.*

JURISDICTIONAL STATEMENT

The Retailers and Distributors agree with Plaintiffs that, because the district court entered final judgments in each of the actions pending on appeal, 28 U.S.C. §1291 provides this Court with appellate jurisdiction over all of these consolidated appeals.

The district court had jurisdiction over each of those actions based on diversity of citizenship under 28 U.S.C. §1332. As explained below, the district court neither did (nor could) take any action that transformed the thousands of individual actions in this multidistrict litigation (MDL) into a single action lacking complete diversity.

INTRODUCTION

The tens of thousands of appeals now before this Court arise from an MDL involving ranitidine, the active ingredient in Zantac and its generic versions. Plaintiffs suffered an across-the-board defeat, losing their claims against retailers and distributors of ranitidine (the Retailers and Distributors) on two independent grounds—preemption and failure to present expert evidence of causation.

Having lost on the merits, Plaintiffs now open their briefing by asking for a do-over. They insist these tens of thousands of actions must start anew, on the theory that the individual actions *actually* became *one* action (and thus, Plaintiffs say, the district court lacked diversity jurisdiction to issue its rulings and render judgment). Plaintiffs press this theory for the first time in their opening brief—even though they repeatedly confirmed diversity jurisdiction to the district court and to this Court. Plaintiffs' theory not only contradicts their prior arguments, but also contradicts their pleadings, the district court's orders, the Federal Rules of Civil Procedure, and binding precedent. Plaintiffs' about-face is a last-ditch effort to evade the district court's well-reasoned decisions. The district court had jurisdiction to enter final judgments in favor of the Retailers and Distributors. This Court should affirm those judgments.

Each of the actions on appeal in this Court rests on the allegation that ranitidine has a propensity to degrade and cause cancer. Each action rests federal

jurisdiction on complete diversity and raises state-law tort claims against one or more defendants—which variously include brand-name manufacturers (the Brands), generic manufacturers (the Generics), and the Retailers and Distributors.

The district court held that the federal Food, Drug & Cosmetic Act (FDCA) preempts Plaintiffs' claims against the Retailers and Distributors. Because "Plaintiffs do not dispute" that the Retailers and Distributors "would be powerless to cure a design defect in a drug, to make changes to the drug's label, or to issue other warnings without FDA approval," the district court concluded that the Retailers and Distributors "would therefore have no recourse to avoid liability except to stop selling the drug altogether." MDL.Dkt.2513 at 27.[1] Because *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), made it "clear that a 'stop-selling' theory cannot be the basis on which a state law claim survives pre-emption," the district court held that impossibility preemption bars Plaintiffs' claims—a conclusion "[c]ourts have routinely reached" and for which "Plaintiffs provide no authority to the contrary." MDL.Dkt.2513 at 26.

The district court later granted the Brands' Rule 702/*Daubert* and summary judgment motions with respect to Plaintiffs' general causation experts who opined on the five cancers that Plaintiffs hand-picked to litigate (the "Designated Cancers").

[1] This brief refers to MDL docket entries as "MDL.Dkt." and refers to docket entries in this Court's appellate docket (all of which refer to docket entries in appeal No. 21-12618) as "CA11.Dkt."

The district court held that: "Plaintiffs have not met their burden to show that their experts relied upon any form of reliable primary evidence in support of their general causation opinions" that ranitidine causes cancer. MDL.Dkt.6120 at 321.

The district court then issued show-cause orders under Federal Rule of Civil Procedure 56(f) that gave all personal injury Plaintiffs an opportunity to explain why its rulings should not apply to their specific action, MDL.Dkt.6444, or to a particular defendant, MDL.Dkt.6303. Plaintiffs answered those orders by collectively filing a *single* response that did not address any individual plaintiff and identified no other experts whose testimony Plaintiffs might seek to admit. MDL.Dkt.6540. The district court thus held that its summary judgment decision should apply against all Plaintiffs in favor of all Defendants. MDL.Dkt.6622. The Clerk then entered Rule 58 final judgments in favor of Defendants in each of the tens of thousands of individual actions in the MDL, which, with respect to the Retailers and Distributors, are based on both preemption and each plaintiff's failure to offer sufficient admissible evidence that ranitidine caused their alleged cancer. MDL.Dkt.6974.

Plaintiffs appealed these final judgments. Their lead argument is the newfound theory that the district court lacked diversity jurisdiction because the tens of thousands of individual actions in this MDL somehow became a *single* action. Omnibus Br. at 26; Generics-Only Br. at 19-27. As Plaintiffs themselves previously admitted, this theory is meritless: The "Federal Rules only allow separate actions to

be joined into a single action" if "the parties seeking joinder … meet the standard of Rule 20[,]" and here "[n]o party to *any action* ever invoked, discussed, or even referenced Rule 20." CA11.Dkt.265 at 4-5. Indeed, Plaintiffs' master complaint "names no plaintiffs" and explicitly states that "it 'is *not* intended to consolidate for any purpose the separate claims of the individual Plaintiffs in this MDL,'" and it "does *not* constitute a waiver or dismissal of any actions or claims asserted in those *individual* actions." *Id.* at 12 (quoting MDL.Dkt.887 at 2).

On the merits, the district court's preemption ruling alone suffices to affirm the judgments for the Retailers and Distributors. Remarkably, the Omnibus Brief filed on behalf of nearly all Plaintiffs does not address preemption at all, but—in violation of the Court's consolidation order—purports to incorporate by reference an argument made in Plaintiffs' "Generics-Only" Brief. Omnibus Br. at 27. That brief, filed by 18 plaintiffs who sued only one or more of the *Generics*, does not mention (let alone address) preemption as to the *Retailers and Distributors*, Generics-Only Br. at 27–43, and does not touch on two of the grounds on which the district court rested its preemption rulings in favor of the Retailers and Distributors. And Plaintiffs' preemption argument—that their claims "parallel" federal law because they allege "that ranitidine is 'dangerous to health," *id.* at 49—fails on the merits in any event because it is irreconcilable with *Bartlett* and the basic preemption principles upon which *Bartlett* rests.

Further, the district court's summary judgment decision provides a separate, independently sufficient ground for affirmance. The correctness of that decision is explained in the Brands' brief, which the Retailers and Distributors incorporate by reference. *See* Fed. R. App. P. 28(i). And as explained below, the district court properly conducted a show-cause process that resulted in summary judgment in favor of the Retailers and Distributors and against every Plaintiff in the MDL that presented a claim against a retailer or distributor.

STATEMENT OF ISSUES

This brief addresses three issues raised by Plaintiffs that pertain to the Retailers and Distributors:

1. Did the district court correctly exercise diversity jurisdiction over the thousands of individual actions in this MDL?

2. Did the district court correctly hold that impossibility preemption under the FDCA forecloses Plaintiffs' claims against the Retailers and Distributors?

3. Did the show-cause process the district court used to determine whether to apply its summary judgment ruling to individual Plaintiffs comply with the Due Process Clause?

STATEMENT OF THE CASE

I. Federal Regulatory Background

The FDCA provides that before a manufacturer may market a "new drug" in the United States, it must apply for and secure the FDA's approval confirming the

FDA's conclusion that the drug is safe and effective. *See* 21 U.S.C. §§321(p), 355(a). The FDCA sets out two categories of new drug applications—a new drug application (NDA) for brand-name drugs and an abbreviated new drug application (ANDA) for generic versions of those drugs. 21 U.S.C. §355(b) and (j).

An NDA must contain, *inter alia*, information about the composition and specifications of the drug, "reports of [the clinical] investigations", 21 U.S.C. §355(b)(1)(A)(i), and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product", 21 C.F.R. §314.50(d)(1)-(2) and (5)(iv). The NDA must also contain "the labeling proposed to be used for such drug," 21 U.S.C. §355(b)(1)(A)(vi); *see* 21 C.F.R. §314.50(c)(2)(i), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. §314.50(d)(5)(viii); *see* 21 C.F.R. §314.50(c)(2)(ix).

The FDA may approve the NDA if it determines, *inter alia*, that (i) the drug is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof" and (ii) "the drug will have the effect it purports or is represented to have" in the proposed labeling. 21 U.S.C. §355(d). Because "[n]o drug is absolutely safe" and "all drugs have side effects," FDA, *FDA's Drug Review Process: Continued* (Aug. 24, 2015),[2] the FDA "generally considers a drug safe

[2] https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-continued.

when the expected therapeutic gain justifies the risk entailed by its use," *United States v. Rutherford*, 442 U.S. 544, 555 (1979); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000) (explaining that a drug's "probable therapeutic benefits must outweigh its risk of harm").

After a brand-name drug's NDA has been approved and listed by the FDA (*see* 21 U.S.C. §355(j)(7)), and following exclusivity periods (*see* 21 U.S.C. §355(j)(5)(F)), any manufacturer may seek approval to market a generic version of the drug, *see* 21 U.S.C. §355(j)(7), (j)(5)(F). An ANDA applicant must show that the generic drug is the brand-name drug's "pharmaceutical equivalent" (*i.e.*, it has the "same" active ingredient(s), route of administration, dosage form, and strength) and "bioequivalent" (*i.e.*, it has the equivalent "rate" and "extent" of absorption), and that it is labeled for the same conditions of use previously approved for the brand-name drug. 21 U.S.C. §355(j)(2)(A)(ii)–(iv) and (8)(B); 21 C.F.R. §320.21(b). The generic drug must have the "same" warning labeling as its brand-name counterpart. 21 U.S.C. §355(j)(2)(A)(v). That duty of sameness for the drug's composition and labeling continues so long as the generic is marketed.

After the FDA has approved either an NDA or ANDA, a manufacturer may not unilaterally make any major "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients." 21 C.F.R. §314.70(b)(2)(i); *see* 21 C.F.R. §314.3 ("drug substance"). However, the FDCA's

"'changes being effected'" procedure allows a brand manufacturer to make unilateral label revisions to "'add or strengthen a contraindication, warning, [or] precaution.'" *Wyeth v. Levine*, 555 U.S. 555, 568 (2009) (quoting 21 C.F.R. §314.70(c)(6)(iii)). Thus, in certain circumstances a *brand manufacturer* may unilaterally strengthen a warning, subject to the FDA's subsequent *dis*approval. *Id.*

As explained in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (discussed below), the ability to unilaterally implement a label change is solely the prerogative of brand manufacturers. It is denied even to generic manufacturers. Generic manufacturers may change their labeling *only* "to match an updated brand-name label or to follow the FDA's instructions." *Id.* at 614. Otherwise, a generic manufacturer's "duty of sameness" precludes it from making unilateral changes to the composition of the drug or its label.

The FDA maintains continuing oversight over approved drugs. After an NDA or ANDA is approved, the applicant must maintain records and make reports to the FDA. 21 U.S.C. §355(k)(1). For example, an applicant must promptly report serious adverse events associated with use of its drug and periodically submit new information that may affect the FDA's previous conclusions about the drug's safety or effectiveness. 21 C.F.R. §§314.80, 314.81, 314.98. The FDA has authority in certain circumstances to require a brand-name drug manufacturer to conduct post-approval studies or clinical trials to assess safety risks or to order any drug

manufacturer to make labeling changes to address new safety information. 21 U.S.C. §355(*o*)(2)(B), (3) and (4).

The FDCA provides that the FDA shall withdraw approval of a drug if it determines that the drug is "unsafe for use" under the conditions stated in its labeling or that the drug does not have its purported effect. 21 U.S.C. §355(e). In addition, the FDA has continuing oversight of approved drugs under the FDCA's provisions prohibiting the manufacture, distribution, or receipt of a drug that is "misbranded." 21 U.S.C. §331(a)–(c), (g), and (k). A drug is misbranded, *inter alia*, if "its labeling is false or misleading in any particular," or if it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. §352(a), (j), (n); *see also id.* §§321(n), 331(a), (b), (k).

The FDA is empowered to enforce all these provisions through injunction, seizure, and even penalties. 21 U.S.C. §§332–35. But the FDA often proceeds informally instead. For example, the FDA can call the manufacturer's attention to potential problems, prompting a voluntary recall. *See* 21 C.F.R. §7.45. The FDA may also request a "market withdrawal" when an issue arises which "would not be subject to legal action by the Food and Drug Administration or which involves no violation." *Id.* §7.3(j); *see also* Letter of Janet Woodcock, U.S. Food & Drug Admin., Dkt. No. FDA-2020-P-0042 at 6 (Apr. 1, 2020). The FDCA authorizes no

private cause of action, and proceedings to enforce its rules on drugs—whether for injunction, seizure, or penalties—can be pursued only by the federal government. 21 U.S.C. §337(a).

While downstream entities, including Retailers and Distributors, are subject to the FDA's enforcement powers for directing prospective relief (injunction and seizure), two statutory safe harbors shield these downstream entities from penalties (which address conduct retrospectively). First, a party is exempt from penalties "if he establishes a guaranty" signed by the person "from whom he received [the drug] in good faith" to the effect that the article is not adulterated or misbranded. 21 U.S.C. §333(c). Second, a party is exempt from penalties if he delivered or proffered the drug "in good faith" and "furnish[ed] on request ... the name and address of the person from whom he purchased or received" the drug. *Id.* Plaintiffs have never alleged or argued that the Retailers and Distributors had knowledge of any defect in ranitidine or its labeling; or that their conduct, which relied in good faith on the FDA's safe-and-effective determination, falls outside these safe harbors.

II. The Retailers' and Distributors' Roles in the Supply Chain

Starting with the manufacturer and ending with the consumer, the drug supply chain involves several groups of actors. Retailers, pharmacies, and wholesale distributors each play a role. Distributors generally enter into agreements with manufacturers through which they purchase pharmaceutical products directly.

Distributors then enter separate agreements with retailers, through which distributors fill retailers' purchase orders (often daily). Distributors ordinarily do not have contact with the end users of the products that they distribute.

Retailers provide drugs to end users, both by prescription and over-the-counter. The Retailers (as defined here) include entities that sold over-the-counter ranitidine (in either branded or generic form) and pharmacies employing licensed pharmacists that dispensed branded or generic prescription ranitidine in accordance with physicians' prescriptions (as well as entities that both dispensed prescription ranitidine and sold over-the-counter ranitidine).[3]

Neither the Retailers nor the Distributors have any ability, right, or obligation to control the design, manufacture, or labeling of FDA-approved drugs. That is true generally and is assuredly true based on the allegations in this case related to ranitidine. Plaintiffs "concede" they have not alleged that the Retailers or the Distributors had any knowledge of ranitidine's alleged defect. MDL.Dkt.3683 at 88:11-89:4. Plaintiffs have also acknowledged that "there is nothing a retailer or distributor could do to ... catch" a defect in the product. MDL.Dkt.2499 at 107:19-108:5. And, last but not least, "Plaintiffs have represented that there *are no* state-law

[3] The chain of distribution is documented through the provisions of the Drug Supply Chain Security Act, 21 U.S.C. §360eee, which facilitates the tracing of transactions along the supply chain. That Act requires that anyone along the supply chain, including the Retailers and Distributors, receive documentation that the supplier "did not knowingly ship a suspect or illegitimate product." 21 U.S.C. §360eee(27)(D).

duties as to the Retailer [and Distributor] Defendants. MDL.Dkt.2513 at 32 (emphasis in original); *id.* at 32 n.12 (explaining implied inclusion of Distributors).

III. The FDA's Actions Related to Ranitidine

As noted above, these appeals involve ranitidine, the active ingredient in brand-name Zantac and its generic versions. GlaxoSmithKline first developed and patented Zantac, and the FDA first approved the sale of prescription Zantac in 1983, MDL.Dkt.887 ¶¶ 225, 230–31. In 1995, the FDA approved the sale of over-the-counter Zantac. *Id.* ¶233. And when the patents on Zantac expired, various manufacturers, following the ANDA process, began to produce generic ranitidine products in both prescription and over-the-counter forms. *Id.* ¶¶249–51.

Plaintiffs allege that ranitidine can degrade into a molecule called N-nitrosodimethylamine (NDMA), and allege that ingesting NDMA can increase the risk of cancer. *Id.* ¶¶253, 264–72, 321, 324, 331.

In 2019, a Citizen Petition was filed with the FDA calling for a recall of all ranitidine products due to the presence of NDMA. MDL.Dkt.6120 at 2. On September 13, 2019, the FDA issued a statement explaining that it had become aware that some ranitidine products may contain "low levels" of NDMA. MDL.Dkt.6188-8 at 1. And on November 1, 2019, the FDA announced that testing revealed the presence of NDMA in ranitidine products, explaining that "the levels

of NDMA in ranitidine … are similar to the levels" that a person would consume by eating "grilled or smoked meats." MDL.Dkt.6188-13 at 2.

Plaintiffs allege that the FDA initially recommended that drug manufacturers recall products with NDMA levels above the FDA's conservative acceptable daily intake level. MDL.Dkt.887 ¶296. And Plaintiffs allege that six months later, on April 1, 2020, the FDA requested voluntary withdrawal of all ranitidine products from the market. *Id.* ¶301; *see also* MDL.Dkt.6188-15 at 1. Plaintiffs do not allege that any defendant failed to follow the FDA's recommendation.

IV. Procedural History

The above events prompted a spate of lawsuits in which plaintiffs alleged personal injury from alleged exposure to NDMA in ranitidine products. On February 6, 2020, pursuant to 28 U.S.C. §1407, the United States Judicial Panel on Multidistrict Litigation created an MDL, ordering that all federal actions involving such allegations be transferred to the Honorable Robin L. Rosenberg of the U.S. District Court for the Southern District of Florida for all pretrial purposes. MDL.Dkt.1 at 3. Since that time, thousands of additional plaintiffs have filed lawsuits in, or had their lawsuits transferred to, that district court.

In addition, the district court created a registry of individuals with potential claims. Claimants who participated in the registry received the benefit of tolled statutes of limitations (pursuant to the Defendants' agreement), and "[i]n

exchange …, the Claimants were required to file their claim, should they ever elect to file, in federal court." MDL.Dkt.7308 at 2. *See also* MDL.Dkt.547 at 11; MDL.Dkt.6140 at 15 (noting that [a]pproximately 80% of the Claimants" in the registry certified, under penalty of estoppel, that they would file in federal court). And prior to transferring their claims from the registry to the MDL (by filing a Short Form Complaint), registry Claimants certified under penalty of estoppel "that federal court jurisdiction exists over his or her claims" and agreed that they "must not name a defendant with the same state of citizenship[.]" MDL.Dkt.5348 at 3.

A. Pretrial Order 31 and the Master Complaint

In light of the large number of actions transferred to the MDL, "and the inefficiencies of drafting unique complaints and individual answers to those complaints, the Parties … agreed to" a series of procedures involving the use of master pleadings. MDL.Dkt.1496 at 1. Pretrial Order (PTO) 31 set forth these procedures, which like many MDLs required the use of a single master personal injury complaint (the MPIC) to set forth common allegations and individual Short Form Complaints (SFCs) filed by each plaintiff. *Id.* at 2–3. In particular, PTO 31 required each SFC to state the individual plaintiff's name, the specific injuries alleged, the specific defendants named, the specific portions of the MPIC adopted by reference, and any "[a]dditional allegations or causes of action not pleaded in the [MPIC]." *Id.* PTO 31 also prohibited multi-plaintiff complaints and required any

plaintiff seeking to make an amendment that "would … destroy diversity" to first obtain the district court's permission. *Id.* at 5. PTO 31 further provided that "[f]or each action directly filed in or transferred to [the] MDL …, *the [MPIC] together with the [SFC] shall be deemed the operative Complaint*." *Id.* at 3 (emphasis added); *see also* MDL.Dkt.6787 at 9 (explaining that "it is the Short Form Complaint that controls and governs diversity—each Plaintiff chooses the specific Defendants that he or she names as Defendants in the Short Form Complaint").

In accordance with PTO 31, Plaintiffs filed an MPIC that named no plaintiffs and that "set[] forth allegations of fact and law common to the personal-injury claims", which the SFCs then incorporated by reference. MDL.Dkt.887 at 1. Each of the MPIC's claims rested on the allegation that the proclivity of ranitidine to break down into NDMA, and the failure to warn or address that fact in ranitidine's design and labeling, rendered ranitidine unreasonably dangerous. *Id.* at 100–43.

Notably, the MPIC expressly stated that it was "not intended to consolidate for any purpose the separate claims of the individual Plaintiffs in this MDL," and did "not constitute a waiver or dismissal of any actions or claims asserted in those individual actions[.]" *Id.* at 2. The MPIC also recognized that the district court had diversity jurisdiction: "In each of the *actions* there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $75,000.00, exclusive of interest and costs." *Id.* ¶216 (emphasis added).

B. The district court's orders dismissing the original MPIC

Defendants responded with a number of motions to dismiss, all of which were directed at the MPIC—not the SFCs. And the district court issued several orders that in large part granted these motions.

In one dismissal order, the district court dismissed the MPIC in its entirety as an impermissible shotgun pleading. MDL.Dkt.2515 at 13. This dismissal was without prejudice and with leave to amend to correct the shotgun-pleading problems. *Id.* In another dismissal order, the district court ruled that only Massachusetts and California courts would recognize a duty by brand-name manufacturers to consumers of generic ranitidine (*i.e.*, innovator liability). *See* MDL.Dkt.2516 at 14. The district court thus dismissed innovator liability claims brought by non-California or Massachusetts plaintiffs, but granted those same plaintiffs leave to amend "to plead a prima facie case of personal jurisdiction in California and Massachusetts." *Id.* at 8, 24.

The district court also granted the Generics' and the Retailers and Distributors' motions to dismiss based on federal preemption. MDL.Dkt.2512; MDL.Dkt.2513. The district court dismissed with prejudice Plaintiffs' claims against the Generics "based on alleged product and labeling defects", but granted Plaintiffs "leave to replead claims against [Generic] Defendants based on expiration

dates, testing, storage and transportation conditions, warning the FDA, [and] manufacturing defects[.]" MDL.Dkt.2512 at 53.

In a separate order, the district court dismissed with prejudice all but one of Plaintiffs' claims against the Retailers and Distributors. MDL.Dkt.2513. It held that because federal law barred the Retailers and Distributors from changing the composition, labels, or warnings for the ranitidine they sold, federal law preempted the state-law claims against them. *Id.* at 30. In doing so, the district court rejected Plaintiffs' various theories for evading preemption, including their parallel misbranding theory—the only theory Plaintiffs even arguably raise on appeal as to the Retailers and Distributors. *Id.* The district court rejected this theory on four independent grounds. *Id.*

First, the district court concluded that the Retailers and Distributors could not alter the composition of the drug or its label *and* that, even assuming misbranding, "Plaintiffs have not plausibly alleged that [the Retailers and Distributors] *knew* that the drugs were misbranded"; thus, their only recourse was to stop selling the drug altogether, which was not required to comply with state law. MDL.Dkt.2513 at 30 (citing *Bartlett*, 570 U.S. at 488–91). Second, following *Bartlett*, "courts have only entertained the possibility of misbranding-based claims when the claims were 'pure-design defect claims'"—but such a hypothetical claim, could "only be brought against a manufacturer—not a retailer or a distributor." *Id.* (citations omitted). Third,

Plaintiffs' parallel misbranding theory would "render the vast body of pre-emption caselaw in the drug context, including binding Supreme Court decisions, meaningless" because it would allow any plaintiff to avoid preemption by asserting that a drug's label was either "false or misleading" or that the drug was "dangerous." *Id.* at 31. Fourth, Plaintiffs could not "create a private right of action to enforce federal misbranding rules by disguising it as a state-law strict-liability claim." *Id.* at 31–32.

While the FDCA preempted most of Plaintiffs' claims against the Retailers and Distributors, the district court concluded that a "general negligence" claim "not based upon (i) the adequacy of an FDA-approved label or (ii) the design of ranitidine" may fall outside FDCA preemption. *Id.* at 39. The district court therefore granted Plaintiffs leave to amend to allege such a claim against the Retailers and Distributors—*e.g.*, a claim for "le[aving] Ranitidine on a hot truck in the Arizona desert." *Id.* at 35.

C. The *Cartee* appeal

Following the dismissals of the MPIC (and before Plaintiffs filed any amended MPIC), two individual plaintiffs—represented by the same lead counsel representing Plaintiffs in the currently pending appeals—tried to get immediate appellate review of the district court's orders. The first plaintiff, Arthur Cartee, filed an amended SFC that alleged *only* an innovator liability claim against a subset of the

Brands—though it still incorporated the allegations in the then-dismissed MPIC—and then *immediately appealed while his amended SFC was still pending in the district court*. *See In re Zantac (Ranitidine) Prods. Liab. Litig. ("Cartee")*, No. 21-10305, 2022 WL 16729151, at *2–3 (11th Cir. Nov. 7, 2022).

The second plaintiff, Marilyn Williams, followed a similar tactic. Like Cartee, Williams "filed an amended SFC after the dismissal of the MPIC and before the filing of an amended MPIC." *Id.* at *3. Seeking to obtain immediate appellate review of the district court's preemption decisions, Williams amended her SFC to limit her claims to *only* a design-defect theory, and then voluntarily dismissed her amended SFC without prejudice under Rule 41(a)(1)(A)(i). *Id.* She asserted that the district court's preemption orders "were made final with respect to [her] … when [she] amended her Short Form Complaint to eliminate all claims for which repleading was permitted by the Court's Orders." *Id.*

The Brands moved to dismiss Cartee's and Williams' appeals for lack of appellate jurisdiction and raised two separate and independently sufficient arguments for doing so. First, the Brands argued that the district court *never dismissed* Cartee's and Williams' SFCs: Cartee's amended SFC remained pending, while Williams voluntarily dismissed her amended SFC without prejudice (and without-prejudice voluntary dismissals do not qualify as final, appealable decisions). *See Cartee*, CA11 Appeal No. 21-10305, Dkt.18 at 13–15; *Williams*, CA11 Appeal

No. 21-10306, Dkt. 36 at 17–19. Second, the Brands argued that Cartee's and Williams' actions had "merged" with the other actions in the MDL under Footnote 3 of *Gelboim v. Bank of America Corp.*, 574 U.S. 405, 413 n.3 (2015), and that they thus could not appeal until *every* Plaintiff's claims were resolved. *See Cartee*, CA11 Appeal No. 21-10305, Dkt. 18 at 9–12; *Williams*, CA11 Appeal No. 21-10306, Dkt. 36 at 11–14.

Cartee and Williams opposed dismissal and challenged the Brands' "merger" theory, arguing that if the actions had been "merged," the MDL must be dismissed for lack of complete diversity. *See Cartee*, CA11 Appeal No. 21-10305, Dkt. 23 at 15; *Williams*, CA11 Appeal No. 21-10306, Dkt.45 at 15. Cartee and Williams insisted that the actions had *not* been "merged." They argued that nothing in the district court's pretrial orders or the MPIC itself "suggest[ed] that by incorporating MPIC allegations, personal-injury plaintiffs [merged] their *separate* actions into a *single* one"; rather, the "MPIC [was] a menu of available defendants, facts, and counts that individuals *may* incorporate into SFCs, and, *so incorporated*, it [became] the pleading for *that* plaintiff." *Cartee*, CA11 Appeal No. 21-10305, Dkt.23 at 11–12; *accord Williams*, CA11 Appeal No. 21-10306, Dkt. 45 at 12.

After holding oral argument in the *Cartee* and *Williams* appeals, this Court ordered supplemental briefing on the diversity-jurisdiction question. Cartee and Williams again argued that the thousands of individual actions remained separate.

They noted "multiple actions become a single action only when the parties are *joined*[,]" which can occur only via either of two mechanisms—"by a motion to join parties or through an amended pleading, but in either scenario, the parties seeking joinder must meet the standard of Rule 20." *Cartee*, CA11 Appeal No. 21-10305, Dkt.79 at 1. Because there had been no motions or rulings on joinder under Rule 20, they explained, the MDL's tens of thousands of actions necessarily remained separate. *Id.* at 2–3. Citing the language in the district court's pre-trial orders and the MPIC itself, Cartee and Williams further pointed out that the intent of the parties and the district court was always to preserve each action's individual identity. *Id.* at 3. And they noted that, unlike the MPIC, each individual plaintiff was charged a $400 filing fee for their SFC and received their own civil case number. *Id.* at 4.

On November 7, 2022, this Court dismissed both *Cartee* and *Williams* for lack of appellate jurisdiction. The Court did so on the basis of the Brands' *first* argument: Cartee "cannot unilaterally declare his second amended SFC dead when the district court has not done so, and he cannot deny that this SFC is still alive and pending in the district court"; Williams improperly sought "to appeal matters related to the very claim she voluntarily dismissed[.]" *Cartee*, 2022 WL 16729151, at *5. Notably, the Court also implicitly *rejected* the Brands' alternative merger theory, pointing out that "[a]n individual plaintiff like Mr. Cartee *does not necessarily need to wait for the resolution of the entire MDL to appeal*. The district court could dismiss his

amended SFC *sua sponte* (or on motion) in light of its rulings on the MPIC, but it has not done that." *Id.* at *4 (emphasis added).

Following this Court's decision, Williams filed a certiorari petition, which the Supreme Court denied. *See Williams v. Boehringer Ingelheim Pharms., Inc.*, 144 S. Ct. 1001 (2024). Meanwhile, Cartee returned to the district court and requested that it "dismiss his operative short-form complaint with prejudice and direct the clerk to enter judgment under Rule 58." MDL.Dkt.6223 at 2. The district court denied Cartee's request for multiple reasons, including that no defendant had moved to dismiss his SFC, and that Cartee's SFC did not comply with PTO 31 because it still incorporated claims from the original, long-defunct MPIC. MDL.Dkt.6317 at 1–2.

D. The district court's orders dismissing the amended MPIC and the subsequent appeals

While the *Cartee* appeal proceeded, Plaintiffs filed their Amended MPIC, which, among other things, raised a "general negligence" claim against the Retailers and Distributors—Plaintiffs' sole remaining claim against these Defendants. MDL.Dkt.2759 at 435–70. The district court later dismissed this claim with prejudice as implausibly pled, noting Plaintiffs' concession that the amended MPIC does not make supporting factual allegations and failed to allege any "concrete specific act of negligence (such as an overheated store, truck, or warehouse)[.]" MDL.Dkt.3716 at 10. Plaintiffs have not challenged this dismissal on appeal. The

district court also dismissed with prejudice Plaintiffs' amended claims against Generics, again on preemption grounds. MDL.Dkt.3750.

Following its dismissal orders, on November 1, 2021, the district court entered Rule 58(a) final judgments in several "Generic-Only" actions—*i.e.*, actions in which Plaintiffs had named only one or more generic manufacturers as defendants. *See* MDL.Dkt.4595. The district court explained that it had dismissed all claims against the Generics in the master complaint with prejudice, and while "Pretrial Order # 31 permitted the Plaintiffs to bring claims not pled in the master complaints in their Short Form Complaints," an "opportunity to amend … can be waived" by filing a notice of appeal. *Id.* at 23–24. Because 18 "Generic-Only" Plaintiffs filed notices of appeal, the district court entered Rule 58(a) final judgments in these 18 actions. MDL.Dkt.4664; MDL.Dkt.4664-1.

In explaining its rationale for issuing these Generic-Only final judgments, the district court *rejected* the notion that the cases were "merged" under *Gelboim* Footnote 3, reasoning that "the merger doctrine is ultimately founded on the common-sense principle that if a party elects to waive an individual right, the party may do so." MDL.Dkt.4595 at 21. Noting "both the usage of Short Form Complaints in Pretrial Order # 31 and the Plaintiffs' express disavowal of the merger doctrine in their master pleadings," the district court concluded Plaintiffs had not intentionally waived "their individual appellate rights." *Id.* at 22. It thus entered the final

judgments to permit the 18 Generic-Only Plaintiffs to immediately appeal. *Id.* These are the 18 actions for which this Court's December 26, 2023, briefing and consolidation order provided for separate briefing. *See* CA11.Dkt.355-1 at 2.

As for the Retailers and Distributors, the district court concluded that it could not enter Rule 58(a) final judgments in actions involving them because its dismissal orders did not "preclude *individual Plaintiffs, in their own cases*, from seeking to plead a negligence claim on case-specific facts." MDL.Dkt.4595 at 12 (emphasis added; quotation marks and citation omitted); *see also id.* at 5–6 (explaining that *the SFCs* "*that each individual Plaintiff files are also operative pleadings*" and are "a theoretical vehicle for an individual Plaintiff to plead claims not pled in the master complaints" (emphasis added)). That said, the district court did enter Rule 54(b) partial final judgments as to the Retailers and Distributors, explaining that "[a]ll of the parties affected by the Court's federal pre-emption rulings—not just a subset of the Generics—should have the opportunity to argue the propriety of that ruling in a single, binding appellate forum[.]" *Id.* at 30; MDL.Dkt.4665.

Once the appeals of these Rule 58 and Rule 54(b) judgments were before this Court, the Court raised several jurisdictional questions, one of which concerned "whether [the potential merger of the individual actions] affected the district court's jurisdiction over the proceedings, such that its subsequent orders were *ultra vires*."

CA11.Dkt.262-2 at 1.[4] In responding, the Retailers and Distributors stated that "[n]either coordination or consolidation under the MDL statute … nor the adoption of a master complaint modifie[d] the individual cases transferred and consolidated in the MDL into something other than 'civil actions' brought by 'citizens of different States' over which the court has jurisdiction pursuant to 28 U.S.C. § 1332." CA11.Dkt.266 at 8.

The Retailers and Distributors' response specifically explained that PTO 31 left "no doubt that the parties and the District Court intended the individual actions to retain their separate identities for purposes of subject-matter jurisdiction." *Id.* at 9. And in a sentence Plaintiffs now mischaracterize, *see* Generics-Only Br. at 35 n.6, the Retailers and Distributors noted *Gelboim*'s observation that "the court 'may treat the master pleadings as merging the discrete actions for the duration of the MDL pretrial proceedings,' such that an 'order disposing of one of the [temporarily

[4] The Court also inquired whether the district court's Rule 54(b) judgments were proper. CA11.Dkt.262-2 at 1–2. In response, the Retailers and Distributors pointed out that the Rule 54(b) judgments were improper because the district court had, at that time, left one claim still live (the individualized "general negligence" claim) and had thus not disposed of all the claims against the Retailers and Distributors. CA11.Dkt.266 at 17–18 (citing *Lloyd Noland Found., Inc. v. Tenet Health Care Corp.*, 483 F.3d 773 (11th Cir. 2007) (a Rule 54(b) judgment requires all legal theories related to the same claim for relief to be designated as final)). The district court later acknowledged this defect in its Rule 54(b) order. MDL.Dkt.6310 at 9. The district court set forth a deadline for any individual plaintiff to tender a negligence claim against any specific retailer or distributor. No plaintiff made such a tender, and the district court deemed any such claim barred. *See id.* at 3–4.

merged] cases' will not qualify as 'an appealable final decision.'" CA11.Dkt.266 at 8 (quoting *Gelboim*, 574 U.S. at 413 n.3). The Retailers and Distributors emphasized, however, that whatever significance *Gelboim* Footnote 3 has "with respect to finality and the timing of appeals[,]" it certainly "does not suggest that a temporary merger can divest a court of diversity jurisdiction." *Id.*

Plaintiffs' response likewise explained that the district court has always had diversity jurisdiction over the tens of thousands of actions in the MDL. As they argued before the panel in *Cartee*, Plaintiffs noted that no party "ever invoked, discussed, or even referenced Rule 20[,]" that "no one can seriously maintain" all of the MDL's actions satisfy Rule 20's joinder requirements, that the MPIC specifically states Plaintiffs' intention to preserve their individual actions, that the parties and the district court "were keenly aware of the need to maintain diversity[,]" and that the district court's orders reflected the separate nature of each individual action. CA11.Dkt.265 at 5–9.

E. The Rule 702/summary judgment ruling, show-cause process, and entry of final judgments

Meanwhile, in accordance with the district court's scheduling order, on January 8, 2021, Plaintiffs disclosed the types of cancers for which they would provide expert reports supporting their general causation allegations. *See* MDL.Dkt.875 at 3; MDL.Dkt.6120 at 14–15. Plaintiffs' initial list of "designated cancers" eventually winnowed from ten to five: bladder, esophageal, gastric, liver,

and pancreatic cancers. *See* MDL.Dkt.6120 at 14–15. All other cancers would be "non-designated cancers," not specifically addressed in the expert reports—or, by extension, the Rule 702/summary judgment motions addressing Plaintiffs' expert testimony regarding their claim that ranitidine causes the five designated cancers. After those issues were resolved, the district court intended to conduct bellwether trials. *See* MDL.Dkt.4683 at 11.

Bellwether trials proved unnecessary, however, because the district court granted the Brands' Rule 702/summary judgment motions, concluding that Plaintiffs' experts "systemically utilized unreliable methodologies with a lack of documentation on how experiments were conducted," failed to substantiate "analytical leaps," lacked "statistically significant data," and lacked "internally consistent, objective, science-based standards for the evenhanded evaluation of data." MDL.Dkt.6120 at 7. And because all of Plaintiffs' claims require them to prove general causation, the district court concluded that summary judgment was warranted as to all of the designated-cancer claims. *Id.* at 336. [5]

After the district court granted summary judgment to the Brands, the Retailers and Distributors began a process designed to allow final judgments to be entered in

[5] The district court also granted judgment with respect to the non-designated cancer claims because, though given the opportunity, neither lead counsel nor any individual plaintiff attempted to offer evidence in support of causation regarding non-designated cancers. *See infra* n.23.

all cases. First, the Retailers and Distributors sought summary judgment, based on lack of general causation, as to the "general negligence" claim, which the district court had not yet precluded and thus remained before it (*i.e.*, was not part of the appeals from the invalid Rule 54(b) judgments). As the district court had recognized prior to issuing its Rule 702 ruling, "'[i]f the Plaintiffs lose on general causation, they will necessarily lose on every claim, including any individualized negligence claim.'" MDL.Dkt.6233 at 7 (quoting MDL.Dkt.4595 at 34–35). Second, the Retailers and Distributors asked the district court for an indicative ruling that if this Court remanded the Rule 54(b) appeals, it would invoke Federal Rule of Civil Procedure 56(f) to consider granting summary judgment for the Retailers and Distributors, as well as Generics, based, *inter alia*, on Plaintiffs' failure to provide evidence of general causation. *Id.* at 9–11.[6]

In response to the Retailers and Distributors' motion (and other parties' motions), the district court issued orders (1) requiring Plaintiffs "to show cause why the Non-Brand Defendants should not receive the entry of summary judgment for the same reasons the Brand Defendants were entitled to summary judgment",

[6] As required by Fed. R. App. P. 12.1, the Retailers and Distributors asked this Court to stay its proceedings to allow the district court to rule on that motion. CA11.Dkt.284. After the district court granted the Retailers and Distributors' request for an indicative ruling, MDL.Dkt.6310, this Court remanded all cases on appeal—except, at Plaintiffs' insistence, the 18 "Generics only" appeals from Rule 58 judgments over which this Court clearly had jurisdiction. CA11.Dkt.333 at 4–5.

MDL.Dkt.6303 at 2, and (2) requiring Plaintiffs "to show cause as to whether summary judgment should be entered against all Plaintiffs in this MDL" without "regard to the date the case was filed." MDL.Dkt.6444 at 2. The district court specifically noted that it created this "show cause process *as the Plaintiffs have requested*." *Id.* at 8 (emphasis added); *see also* MDL.Dkt.6234 at 4 (Plaintiffs requesting that the "Court Should … Use a Show-Cause Process").

All designated-cancer Plaintiffs filed a *single* response to these show-cause orders. MDL.Dkt.6540. As to the first show-cause order, Plaintiffs' response *did not dispute* that the reasoning in the district court's Rule 702 order applies equally to the Retailers and Distributors. Plaintiffs instead made the irrelevant observations that issue preclusion does not apply and that the district court had already dismissed Plaintiffs' claims against the Retailers and Distributors. *Id.* at 11–12. As to the second show-cause order, Plaintiffs argued that "some Plaintiffs only filed suit after the close of expert discovery of the excluded experts" and complained that "[t]hose Plaintiffs … have had no opportunity to submit experts of their own"—and that the district court "set no deadlines for newly filed Plaintiffs to submit experts." *Id.* at 2–3. Plaintiffs' response, however, *neither proffered any experts they wished to submit*, *id.*, nor "provide[d] a reason why any *specific* individual case should not, because of the date the case was filed, receive entry of summary judgment under Rule 56(f)[,]." MDL.Dkt.6622 at 4.

Consequently, the district court entered summary judgment against all Plaintiffs in favor of all Defendants. *Id.* at 21. It explained, "Plaintiffs have … provided no persuasive reason how the Court's Rule 702 decision could have been different or should be different for non-Brand Defendants." *Id.* And it explained that it applied its Rule 702/summary judgment decision against all Plaintiffs because no "Plaintiff came 'forward and show[ed] cause why it should not be applicable' to the individual Plaintiff … the very process," the district court noted, "that the Third Circuit endorsed in" *Home Depot USA, Inc. v. Lafarge N. Am., Inc.*, 59 F.4th 55 (3d Cir. 2023). *Id.* at 6.

Accordingly, on September 26, 2023, the district court "ordered the Clerk of the Court to file a final judgment in thousands of individual cases" in the MDL. MDL.Dkt.6974 at 8. The district court did so to "create a clean record" and to recognize "the identity of each individual case in this MDL", as well as because "*each individual case has its own operative pleading*—a Short Form Complaint—and the Rule 58 final judgment is limited to the Defendants named in each Plaintiff's Short Form Complaint[.]" *Id.* (emphasis added).

After Plaintiffs appealed from the district court's final judgments, the Retailers and Distributors moved to consolidate the various appeals, including the 18 Generics-Only appeals, based on the similar issues they presented. CA11.Dkt.345. Plaintiffs opposed that motion, arguing, *inter alia*, that it "fail[ed] to

respect that each case is distinct[.]" CA11.Dkt.346 at 2. This Court ultimately consolidated the appeals before a single panel and entered a consolidated briefing schedule, pursuant to which the Retailers and Distributors now file this brief. CA11.Dkt.355-1.

STANDARD OF REVIEW

This Court reviews *de novo* a district court order granting a motion to dismiss. *Marrache v. Bacardi U.S.A., Inc.*, 17 F.4th 1084, 1091-92 (11th Cir. 2021). This Court also reviews *de novo* a district court order granting summary judgment. *Affordable Bio Feedstock, Inc. v. United States*, 42 F.4th 1288, 1291 (11th Cir. 2022).

A district court's orders establishing procedures and setting deadlines for arguing motions and raising claims are reviewed only for abuse of discretion. *See, e.g.*, *Destra v. Demings*, 725 F. App'x 855, 859 (11th Cir. 2018) ("We review a district court's decision to enforce the deadlines in its scheduling order for an abuse of discretion.") (citing *Sosa v. Airprint Sys., Inc.*, 133 F.3d 1417, 1418 (11th Cir. 1998)). To the extent Plaintiffs are alleging that something about those procedures rises to the level of a constitutional due process violation with respect to particular plaintiffs, that is an issue of law, reviewed *de novo*.

SUMMARY OF ARGUMENT

Plaintiffs assert that the Retailers and Distributors are liable for selling a drug that was FDA-approved at the time of sale—but that Plaintiffs now claim was harmful. Because the Retailers and Distributors could not change anything about ranitidine, including its labeling, their only viable option to avoid state-law liability would have been to stop selling it. But the Supreme Court has recognized that a defendant "is not required to cease acting altogether in order to avoid liability," for "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" *Bartlett*, 570 U.S. at 488 (quoting *Mensing*, 564 U.S. at 621). And the district court ruled that Plaintiffs have no evidence to support their theory of harm in any event—a ruling the district court properly applied against all Plaintiffs and in favor of all Defendants, including the Retailers and Distributors.

Having lost on two separate grounds, Plaintiffs now question the district court's subject matter jurisdiction. As Plaintiffs previously recognized, however, the MDL's tens of thousands of separate actions were never joined under Rule 20 and were never joined via an amended complaint. The operative pleading is the *conjunction* of the MPIC *and each individual plaintiff's SFC*. Because the actions have remained separate, each action retains complete diversity among the parties.

The district court's preemption ruling alone suffices to support the judgments in favor of the Retailers and Distributors, and the Court should affirm this ruling on three independently sufficient grounds. First, Plaintiffs have forfeited their challenge to this ruling because their entire preemption argument is incorporated by reference from a brief filed by different plaintiffs against different defendants in different appeals—all in violation of this Court's briefing order. Second, Plaintiffs have further forfeited their challenge to this ruling because, in focusing on the district court's preemption rulings as applied to the Generics, they do not address at least two independent bases upon which the district court rejected their parallel misbranding theory as applied to the Retailers and Distributors: They failed to plausibly allege that the Retailers and Defendants knew that ranitidine was misbranded, and their theory cannot apply to retailers or distributors in any event. MDL.Dkt.2513 at 30. Indeed, Plaintiffs never discuss this ruling at all and cite it only three times across their two briefs. *See* Generics-Only Br. at 43; Omnibus Br. at 11, 27. Third, and on the merits, the district court correctly rejected Plaintiffs' parallel misbranding theory because it is foreclosed by *Bartlett* and *Mensing* and is deficient on its own terms as applied to the Retailers and Distributors.

Lastly, Plaintiffs' due process challenge to the district court's show-cause process fails because the late-filing plaintiffs were not deprived of an "opportunity to contest general causation with their own experts and record." Omnibus Br. at 78.

Most every plaintiff participated in the Rule 702 briefing through Leadership Counsel, and further, *every* plaintiff was given the opportunity to show why summary judgment against them was unwarranted. This satisfied due process, and the Rule 702/summary judgment ruling therefore independently supports the final judgment entered against every Plaintiff.

ARGUMENT

I. The Court Should Reject Plaintiffs' Challenge to Diversity Jurisdiction

Plaintiffs brought these tens of thousands of cases, forced Defendants and the district court (not to mention this Court) to spend four years and countless hours responding to them, and eventually lost. Now, they want to start all over on the theory that Plaintiffs' MPIC "merged" the MDL's tens of thousands of cases into a single action—a theory Plaintiffs raised for the first time on appeal and that directly contradicts their prior, repeatedly affirmed position. Generics-Only Br. at 20. The Court should reject this meritless maneuver.

These actions never became a single action. Each action is here because it was filed in federal court based on diversity jurisdiction, which is reflected in the SFC that each plaintiff was required to file and maintain. Plaintiffs did not destroy the separateness of each action by presenting their common substantive allegations in a master complaint (the MPIC)—which, when *combined* with each SFC constituted the operative pleading. Neither did the district court's ruling on common

allegations via a single order destroy diversity. The individual actions were never joined under Rule 20, and the filing of the MPIC did not transform the thousands of individual actions into a single action *sub silentio*. As Plaintiffs themselves have argued throughout this MDL, the district court's pretrial orders and the MPIC itself were replete with references and statements confirming each action's individuality. While Plaintiffs now assert that this Court and the district court have caused them to change their views on diversity jurisdiction, none of the courts' decisions provide any reason to believe the myriad actions in this MDL somehow were converted into a single action.

Further, even if the district court had inadvertently merged the actions and destroyed complete diversity, this Court has authority to un-merge the actions under *Newman-Green, Inc. v. Alfonzo-Larrain*, 490 U.S. 826, 827 (1989). And given the enormous investment of resources the parties, the district court, and this Court have given this litigation (and the obvious unfairness in starting these cases anew), this situation would be a prime occasion for invoking *Newman-Green*.

A. The district court had diversity jurisdiction because this MDL's thousands of actions never became a single, monolithic action

When evaluating complete diversity under the diversity-jurisdiction statute, 28 U.S.C. §1332, the proper unit of analysis is each individual "action." As the Federal Rules of Civil Procedure succinctly state, "[t]here is one form of action--the civil action." Fed. R. Civ. P. 2. Likewise, 28 U.S.C. §1332(a)(1) provides that "[t]he

district courts shall have original jurisdiction of all civil *actions* where the matter in controversy exceeds the sum or value of $75,000 … and is between—citizens of different States[.]" (emphasis added). And 28 U.S.C. §1407(a), which establishes courts' ability to consolidate actions into multidistrict litigation, states that "[w]hen civil *actions* involving one or more common questions of fact are pending in different districts, such *actions* may be transferred to any district for coordinated or consolidated pretrial proceedings." (emphasis added). Accordingly, "[c]ases consolidated for MDL pretrial proceedings ordinarily retain their separate identities[.]" *Gelboim*, 574 U.S. at 413.

1. The actions in this MDL were always understood to be separate and were never joined together into a single action

The Federal Rules of Civil Procedure provide just two ways by which multiple actions can become one action—either by filing a joinder motion under Rule 20 or by filing or amending a complaint that lists every plaintiff in a single action. Both mechanisms require satisfying Rule 20's substantive standard for permissive joinder, and neither has been done here.[7]

Start with Rule 20 joinder. At the district court, there were no motions or rulings to join the individual actions under Rule 20, and none of the parties invoked,

[7] Rule 19(a)(2)'s "required" joinder standard does not apply here because the thousands of individual personal injury plaintiffs are not necessary parties to each other's cases. Plaintiffs do not argue otherwise, including on appeal.

discussed, or even referenced Rule 20. Nor did joinder occur when the cases were consolidated within the MDL. *See, e.g.*, *Hall v. Hall*, 584 U.S. 59, 72 (2018) ("[P]arties to one case did not become parties to the other by virtue of consolidation[.]").

Because no joinder occurred under Rule 20, the only other avenue for joinder to occur within the MDL would be if the very act of filing of the MPIC (or its amended versions) accidentally converted the thousands of individual actions into a single action *sub silentio*. It did not.

In ordinary civil litigation, an amended complaint filed on behalf of multiple plaintiffs creates a single action in which all of those plaintiffs are parties. Unremarkably, the same is true for MDL proceedings. *See In re Refrigerant Compressors Antitrust Litig.*, 731 F.3d 586, 590 (6th Cir. 2013) (concluding individual actions may be merged if parties "treat the master complaint as an operative pleading that supersedes the individual complaints") (cited in *Gelboim*, 574 U.S. at 413 n.3); *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 489 (7th Cir. 2020) ("[P]arties may choose to manage those cases in ways that can change that default rule and give up the separate identities of the original suits transferred to the MDL litigation.").

In *Refrigerant*, the plaintiffs voluntarily chose to join their actions by filing a single complaint that *listed each plaintiff* in the same pleading. *See* Third Consol.

Am. Compl., No. 09-02042, 2012 WL 9494136, ¶¶22–43 (E.D. Mich. July 6, 2012). This was not the case here. Unlike *Refrigerant* and *Bell*, neither of which utilized SFCs or included express language disavowing merger in their master pleadings, MDL.Dkt.4595 at 22, this MDL's docket is replete with evidence that the parties and district court were protective of the separate identities of the MDL actions.

First, any complaint that attempted to join the MDL's tens of thousands of Plaintiffs together would have violated Rule 20, as the various Plaintiffs' claims do not arise from the same "transaction, occurrence, or series of transactions or occurrences." Fed. R. Civ. P. 20(a)(1)(A); *see also, e.g.*, *Foudy v. Indian River Cnty. Sheriff's Off.*, 845 F.3d 1117, 1120 (11th Cir. 2017) (noting district court dismissed complaint under Rule 20 because "[i]t was not readily apparent … how the various claims constituted the same transaction").

The district court concluded as much (in an order unchallenged on appeal) when it refused to allow the registry claimants to file one multi-plaintiff complaint per law firm: "the Plaintiffs are not sufficiently related, factually, for the joinder of their personal injury claims in a single multi-plaintiff complaint. Such a joinder would not 'ease the burden of litigation in groups of similarly situated persons,' it would create an unmanageable, unworkable burden." MDL.Dkt.6258 at 8 (quoting *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014, 1995 WL 428683, at *2 (E.D. Pa. July 17, 1995)). PTO 31, which set out the structure of the MPIC

process, also specifically foreclosed joinder under Rule 20 by ruling that there could be "No Multi-Plaintiff Complaints." MDL.Dkt.1496 at 5; *see also* MDL.Dkt.6229 at 3 (PTO 80 providing that "multi-Plaintiff complaints in this MDL … would be misjoined and therefore will be severed upon filing" with the district court "requir[ing] separate filing fees").

Second, the district court's numerous pretrial orders and the MPIC itself confirm the individuality of the actions. PTO 31, which set out the parameters of Plaintiffs' pleadings, stated that "[f]or each action directly filed in or transferred to MDL No. 2924 subject to this Order," the "operative Complaint" would be the *conjunction* of the MPIC "together with the Short Form Complaint[.]" *Id.* at 3. PTO 31 further required each Plaintiff's SFC to state against which defendant or defendants he or she raised claims, *id.*, and allowed individual plaintiffs to allege claims in their SFCs that were not found in the MPIC, *id.* at 7. Accordingly, while the MPIC superseded "all claims pleaded in any complaint previously filed in or transferred to [the] MDL[,]" *id.* at 2, this did not transform the MPIC into the sole operative complaint for *any* individual case; after all, allowing plaintiffs to bring non-MPIC claims would be nonsensical if the MPIC were the only operative pleading.

In other words, the structure established by PTO 31 was just as it appeared. The common pleading was a convenience for describing and presenting common

allegations and addressing them in subsequent motions, arguments, and decisions. The short form complaints allowed those common allegations to be incorporated by reference while maintaining the separate identity of each individual action—and thereby maintaining diversity jurisdiction.

The structure and language of the MPIC itself likewise confirms that it did not join the individual actions by becoming the sole operative complaint. Structurally, the MPIC lists no named plaintiffs and thus, taken alone, does not meet the basic requirements of notice pleading. *See* Fed. R. Civ. P. 8(a). The MPIC therefore could not alone constitute the operative pleading.

The MPIC also referred back to the individual actions throughout. It unequivocally stated that it was "not intended to consolidate for any purpose the separate claims of the individual Plaintiffs in this MDL," and that it "d[id] not constitute a waiver or dismissal of any actions or claims asserted in those *individual actions*[.]" MDL.Dkt.887 at 2 (emphasis added). Likewise, the MPIC relied on complete diversity as the basis for federal jurisdiction in *each* of the individual actions into which it was incorporated: "In *each of the actions* there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $75,000.00[.]" *Id.* ¶216 (emphasis added). Finally, the MPIC asked for "statutory damages, treble damages and other relief permitted by the laws of the states that will govern *these actions*[.]" *Id.* at 143 (emphasis added).

As Plaintiffs correctly concluded in their supplemental briefing in *Cartee*, the language of PTO 31 and the MPIC is "impossible to square with the diversity-destroying 'monolithic multidistrict action' [now] conjured in a post-hoc effort to defeat … jurisdiction." *Cartee*, CA11 Appeal No. 21-10305, Dkt.79 at 4 (quoting *Gelboim*, 574 U.S. at 413).

Third, the manner in which the individual actions were filed and dismissed in the MDL further confirms that they have always remained separate. PTO 11 provided for direct filing of SFCs, and stated that *each shall be* "*filed as a new civil action*[.]" MDL.Dkt.422 at 1 (emphasis added); *cf.* Fed. R. Civ. P. 3 ("A civil action is commenced by filing a complaint with the court."). This procedure makes no sense under Plaintiffs' newfound "one big action" theory. If the MDL truly were one action, the plaintiffs would merely be joining an existing action rather than initiating a "new civil action[.]" MDL.Dkt.422 at 1. Yet each plaintiff who filed an SFC in this MDL paid a $400 filing fee and received his or her own civil case number. *See, e.g.*, MDL.Dkt.6229 at 3; Civil Cover Sheet, *Chandler v. Sanofi US Servs. Inc.*, No. 20-cv-81865 (S.D. Fla.) at Dkt.1. Conversely, no fees were assessed for filing the MPIC (or amended versions of it).

Indeed, since the filing of the latest Amended MPIC on February 8, 2021, thousands of actions have been added to the MDL. If this were a single action, by

what process were these late-arriving plaintiffs added to the action? Plaintiffs' theory offers no answer.

The district court's approach to dismissals underscores this point. PTO 39 expressly authorized Rule 41(a)(1) dismissals, which "may be used to dismiss only an 'action' *in its entirety*." MDL.Dkt.1497 at 2 (emphasis added by district court) (quoting *Perry v. Schumacher Grp. of La.*, 891 F.3d 954, 958 (11th Cir. 2018)). The district court therefore counseled that "any Plaintiff seeking to dismiss claims and/or drop Defendants named in a [SFC] shall file an amend[ment]." *Id.* at 2–3. Only plaintiffs seeking to "Dismiss[] Entire Actions" were instructed to file a form invoking Rule 41. *Id.* at 3. Yet again, Plaintiffs' theory would render this order incoherent: A plaintiff could not dismiss his action "in its entirety" if he were truly part of a single "monolithic multidistrict" action. *Gelboim*, 574 U.S. at 413.

Fourth, Plaintiffs' treatment of these actions on appeal also underscores their separate identities. Plaintiffs filed multiple notices of appeal listing thousands of individual actions. *See, e.g.*, *Krause*, CA11 Appeal No. 23-13283, Dkt.1, Dkt.3, Dkt.13. Plaintiffs' opposition to the Defendants' motion to consolidate the appeals—which Plaintiffs filed in November 2023—was similarly premised on the (correct) notion that these appeals involved thousands of individual actions. *See* CA11.Dkt.346 at 2 ("The Retailers fail to respect that each case is distinct[.]"). And even the Omnibus Brief that Plaintiffs just filed cannot help recognizing that these

appeals involve "*many thousands of cases.*" Omnibus Br. at i (emphasis added). The actions in this MDL remain separate, and diversity jurisdiction is thus secure.

2. Plaintiffs' proffered reasons for changing their position on jurisdiction are all groundless

Up until they filed their opening briefs on April 10, 2024, Plaintiffs agreed with all of the above. Time and again they affirmed the separate identities of the actions in this MDL, and they repeatedly deemed the "alternative" single-action theory "absurd[.]" *Cartee*, CA11 Appeal No. 21-10305, Dkt.79 at 2; *see also Cartee*, CA11 Appeal No. 21-10305, Dkt.23 at 14. Now, however, Plaintiffs insist that this "absurd" position is in fact necessary. Generics-Only Br. at 34.

To justify this about-face, Plaintiffs cite (1) language in this Court's *Cartee* opinion, (2) the district court's denial of Cartee's motion to dismiss his own complaint, and (3) the district court's use of a show-cause process to determine whether to apply its summary judgment ruling to all designated-cancer Plaintiffs. Plaintiffs do not argue that any of these events *actually transformed* thousands of actions into one action; after all, none of them have anything to do with creating a single action. Instead, Plaintiffs contend these events somehow *imply* that at some still-unspecified point these thousands of actions *accidentally* became a single action. None of these decisions imply anything of the sort.

First, Plaintiffs say the "chief reason [they] changed their view is this Court's holding that the Zantac MDL motion-to-dismiss decisions applied only to the master

complaint, not any short-form complaint." Generics-Only Br. at 20 (citing *Cartee*, 2022 WL 16729151, at *5) (emphasis omitted). Plaintiffs argue that this Court's holding in *Cartee* "necessarily means that the master pleading is an operative pleading, not merely a reference document." *Id.* According to Plaintiffs, if the MPIC were merely a reference document, the district court would not have been able to issue opinions that only affected it, since those rulings would not have affected "any actual, live claims…." *Id.* Therefore, this Court's implicit approval of the district court's order (which affected only the MPIC and not any SFCs) means that the MPIC was the *sole* operative pleading and necessarily included all Plaintiffs.

This argument misunderstands the nature of the pleadings below and the nature of this Court's holding in *Cartee*. As noted, PTO 31 specified that the operative pleading for each action in this MDL is the *conjunction* of the MPIC *together with* each individual SFC. The MPIC operated as a menu, offering each plaintiff a platter of potential allegations and claims to incorporate by reference. In an SFC, an individual plaintiff chooses which allegations and claims to incorporate and supplies additional critical information, including the plaintiff's citizenship, the defendants against whom the plaintiff is asserting claims, and "the causes of action … the Plaintiff(s) adopts … indicated by checking the applicable box[.]" MDL.Dkt.1496 at 3.

Against this backdrop, it is clear that the district court's dismissal orders affected each plaintiff's individual action, since each plaintiff's SFC incorporated at least some of these claims raised in the MPIC. As is standard in MDLs, the district court will analyze motions to dismiss targeting specific claims in the MPIC. If the motion is successful, the court's order will foreclose those claims and invite the plaintiffs to amend their MPIC—which in turn will require SFCs that incorporated the now-dismissed MPIC claims to be amended accordingly. This standard procedure is exactly what happened here. *See, e.g.*, *In re Uber Techs., Inc., Passenger Sexual Assault Litig.*, No. MDL 3084, 2024 WL 1209785, at *1–2 (N.D. Cal. Mar. 20, 2024) (setting forth similar procedure).

This Court's decision in *Cartee* confirms this straightforward understanding of the proceedings below. *Cartee* addressed attempts by two individual plaintiffs (Cartee and Williams) to obtain immediate appellate review of the district court's dismissal orders by amending their SFCs to incorporate only claims in the MPIC that had already been dismissed. 2022 WL 16729151, at *2–3. The Court rejected appellate jurisdiction because Cartee's SFC was still pending in the district court, and because longstanding precedent barred Williams' attempt to create appellate jurisdiction by voluntarily dismissing her SFC. *Id.* at *5. Accordingly, there was "no final ruling putting their operative complaints—the combination of the MPIC and their individual SFCs—to rest." *Id.* at *7.

In reaching that holding, this Court implicitly *rejected* the notion that this MDL constitutes a single action. Throughout the opinion, this Court recognized—contrary to Plaintiffs' newfound position, Generics-Only Br. at 20—that the operative pleading in the MDL was the "combination of the MPIC and [plaintiff's] individual SFCs[.]" *Cartee*, 2022 WL 16729151, at *7; *see also id.* at *4–5.

Most importantly, the Court held that "[a]n individual plaintiff like Mr. Cartee *does not necessarily need to wait for the resolution of the entire MDL to appeal*. The district court *could dismiss his amended SFC sua sponte* (or on motion) in light of its rulings on the MPIC, but it has not done that." *Id.* at *4 (emphasis added). This statement excludes Plaintiffs' single-action theory, because if the MDL constituted a single action, "dismiss[ing] his amended SFC" would not permit Cartee to appeal; Cartee would have instead "need[ed] to wait for the resolution of the entire MDL to appeal." *Id.* In rejecting that notion, this Court thus confirmed the commonsense understanding of this MDL: It consists of thousands of individual actions.

Indeed, the only question raised by the MPIC-plus-SFC procedure was whether a district court order directed at, and purporting to dismiss, common claims as reflected in the master pleading would, *in itself*, and without more, dismiss such claims in each SFC that incorporated such claims. This Court's decision in *Cartee* effectively answered that question for the district court. The district court recognized that, precisely because each action maintained its separate identity, it would enter

judgment on each individual plaintiff's SFC. *See* MDL.Dkt.6787 at 6–7; MDL.Dkt.6974 at 8.

Second, Plaintiffs point to the district court's treatment of Cartee's case on remand, but that too lends their position no support. Generics-Only Br. at 35–36. Following this Court's decision, Cartee asked the district court to "dismiss his operative [SFC] with prejudice and direct the clerk to enter judgment under Rule 58." MDL.Dkt.6223 at 2. The district court denied this request, noting among other points that Cartee's SFC did not comply with PTO 31, since it still incorporated long-since-dismissed claims from the initial MPIC. MDL.Dkt.6317 at 1–2. The district court concluded that "Cartee should have filed an amended Short Form Complaint that used the master pleading that 'supersede[d] and replace[d] all claims pleaded in any complaint previously filed,' the Second Amended Master Personal Injury Complaint at docket entry 3887." *Id.* And it further explained that "Mr. Cartee *could have pled a claim in his [SFC] that was not pled in the master complaints* pursuant to Amended Pretrial Order 31" but "did not do so." *Id.* at 3 n.1 (emphasis added).

Plaintiffs argue that this order makes sense only "if the cases merged[,]" on the theory that if the cases were separate Cartee would be able to "incorporate anything he like[d] by reference into *his* pleading." Generics-Only Br. at 22. Cartee, however, *was able to add anything he liked into his pleading*; as the district court

noted, PTO 31 allowed Cartee to plead a claim in his SFC "that was not pled in the master complaints…." MDL.Dkt.6317 at 3 n.1.

Rather than imply a dramatic reconceptualization of the entire MDL, this order simply enforces PTO 31—an order whose propriety Plaintiffs have not challenged. PTO 31 provided that if a plaintiff chooses to incorporate an MPIC claim, the plaintiff's SFC may incorporate only claims that are listed on the currently live version of the MPIC. Because the original MPIC had been superseded by the amended MPIC, Cartee's SFC violated PTO 31 by purporting to incorporate a claim from a defunct master complaint. PTO 31 allowed Cartee to raise whatever claims he liked; it simply required him to do so by raising "[a]dditional allegations or causes of action not pleaded in the Master Personal Injury Complaint" in his SFC. MDL.Dkt.1496 at 3. It was because he did not do that—and because no defendant had moved to dismiss Cartee's SFC—that the district court denied Cartee's motion. MDL.Dkt.6317 at 1–2.

Third, Plaintiffs' final justification for their change of heart pertains to the district court's show-cause process. Generics-Only Br. at 22–24. Whatever one makes of Plaintiffs' complaints about this process—which, as explained below, are meritless, *see infra* Part III—they certainly do not imply that *these thousands of actions were actually one action*. Just the opposite.

Plaintiffs insist that the district court's use of the phrase "law of the case" when undertaking its show-cause process necessarily implies that there is only one action in this MDL. Generics-Only Br. at 23. Not so. As Plaintiffs acknowledge, the district court undertook its show-cause process "under Rule 56(f)." *Id.* at 24. This rule allows a court to award summary judgment as to any party after *sua sponte* providing notice and an opportunity to respond. The district court's invocation of this Rule thus provides no support for Plaintiffs' theory.

The district court's show-cause process was also proper under the principles set forth in *Home Depot USA, Inc. v. Lafarge N. Am., Inc.*, 59 F.4th 55 (3d Cir. 2023). Precisely because the individual actions in an MDL retain their separate identity, MDL courts employ a show-cause process to extend rulings rendered in one action to another. As the Third Circuit explained in *Home Depot*, "[i]n MDLs, like in other litigation, a district court *may apply prior rulings to new cases* if a party presents no new facts, evidence, or arguments to warrant a departure." *Id.* at 66 n.6 (emphasis added); *see also id.* at 66 (collecting cases).

In short, at every stage of this litigation, the district court and the parties have recognized and preserved the individual identities of the tens of thousands of actions in this MDL. Nothing ever joined these actions together into one "mega action"—which would have violated Rule 20 in any event. Because these myriad actions have remained separate, the parties in each action have remained completely diverse.

Plaintiffs' jurisdictional challenge is a transparent, last-ditch ploy for a wholesale do-over. This Court should reject it.

B. Even if these actions were somehow inadvertently merged, the Court should use its authority to un-merge them

Even if this Court were to conclude that diversity jurisdiction was undermined, it need not vaporize this MDL's years of costly litigation. As Plaintiffs themselves previously explained to this Court, the Court has authority to "sever each case on appeal to cure the jurisdictional defect." CA11.Dkt.265 at 3 n.1 (citing Fed. R. Civ. P. 21; 28 U.S.C. §1653; *Newman-Green*, 490 U.S. at 838). Federal Rule of Civil Procedure 21 authorizes district courts to "at any time, on just terms, add or drop a party." In *Newman-Green*, the Supreme Court held that a court of appeals has analogous authority "to dismiss a dispensable party whose presence spoils statutory diversity jurisdiction." 490 U.S. at 827. If the Court concludes these actions were somehow "merged," it should use its authority to un-merge them such that the cases are "severed in precisely the way Appellants (and the district court) maintain already obtains." CA11.Dkt.265 at 3 n.1.

Notably, the "chief reason" Plaintiffs give for changing their position on jurisdiction is the opinion this Court issued nearly two years ago in *Cartee*. Generics-Only Br. at 20. As explained, *Cartee* provides no support for Plaintiffs' new position, *see supra* I.A.2., but even if it did, why are Plaintiffs only making this argument now?

Even before *Cartee* was issued, Plaintiffs acknowledged that "[i]f the actions were merged, the district court lacked subject matter jurisdiction because many plaintiffs and many defendants listed in the master complaints are from the same state." CA11.Dkt.265 at 2. This Court released its opinion in *Cartee* on November 7, 2022.

Nevertheless, for the following two years Plaintiffs continued to vigorously litigate their claims at the district court and on appeal *without ever suggesting a lack of jurisdiction*. *See, e.g.*, CA11.Dkt.346 (opposing the Retailers and Distributors' motion to consolidate appeals on Nov. 3, 2022). For example, the district court issued its Rule 702 order the month *after* this Court issued its *Cartee* decision, MDL.Dkt.6120, and Plaintiffs spent months disputing the effect of that order (including litigating the show-cause process)—all without ever raising any concern about jurisdiction. *See, e.g.*, MDL.Dkt.6540.

Given the years of party and judicial resources invested in this case, should the Court find any jurisdictional defect it should follow the *Newman-Green* approach. There, after the parties had litigated for several years, the Seventh Circuit panel identified a jurisdictional defect the parties and district court had missed: One of the defendants was "stateless," and that precluded diversity jurisdiction. 490 U.S. at 828. The panel, however, determined this could be cured by "drop[ping] [the stateless defendant] as a party, thereby producing complete diversity" and

retroactively securing the district court's subject-matter jurisdiction. *Id.* at 829. The Supreme Court squarely endorsed this approach over the *en banc* Seventh Circuit's reversal, holding that a court of appeals itself has the power to make the correction. *Id.* at 838. The Supreme Court explained that this approach has both historical backing and enormous practical benefits: "Nothing but a waste of time and resources would be engendered by remanding to the District Court or by forcing these parties to begin anew." *Id.* at 838.

The Supreme Court noted that it is particularly appropriate for appellate courts to exercise this authority to drop dispensable diversity-destroyers where, as here, dismissing the case for lack of jurisdiction would come after "years of litigation" and "impose unnecessary and wasteful burdens on the parties, judges, and other litigants waiting for judicial attention." *Id.* at 836. This Court has applied *Newman-Green* to likewise recognize courts' "authority to retroactively restore complete diversity through a Rule 21 dismissal of a dispensable party." *Mid-Continent Cas. Co. v. JWN Constr., Inc.*, 823 F. App'x 923, 927–28 (11th Cir. 2020); *accord Ingram v. CSX Transp., Inc.*, 146 F.3d 858, 862–63 (11th Cir. 1998). And like the Supreme Court, this Court has emphasized that courts should invoke this authority to avoid "the pointless exercise of dismissing the entire suit, only to have Plaintiff refile in the district court against [properly diverse defendants]." *Id.* at 928.

Severing dispensable parties was appropriate in *Newman-Green* and *Mid-Continent Casualty*, and it is all the more appropriate here. While those cases were fairly run-of-the-mill civil actions involving a small number of parties, this MDL involves tens of thousands of parties who have invested countless hours in the litigation—not to mention the untold time the district court, Clerk's Office, and this Court have devoted to the litigation. If ever there were a proper occasion to invoke *Newman-Green*, this MDL is it. If the Court finds it necessary to restore diversity jurisdiction, the Court should exercise its authority under *Newman-Green* to sever these actions back to their individual status—a status that this Court's and the district court's dockets already recognize.

II. The Court Should Affirm the District Court's Ruling That the FDCA Preempts the Claims Against the Retailers and Distributors

The district court's preemption order in favor of the Retailers and Distributors, MDL.Dkt.2513, supports each of the judgments in their favor. This Court should affirm that order for three independently sufficient reasons.

First, in violation of this Court's consolidation and briefing order, Plaintiffs' entire objection to the district court's Retailers and Distributors preemption ruling is "incorporate[d] … by reference" from an appeal brief filed by *different* plaintiffs against *different* defendants in a *different* appellate docket. Omnibus Br. at 27. Accordingly, as to the Retailers and Distributors, Plaintiffs' preemption arguments are not properly before the Court.

Second, Plaintiffs have failed to challenge at least two independent bases upon which the district court rejected Plaintiffs' parallel misbranding theory as applied to the Retailers and Distributors and granted the Retailers and Distributors' motion to dismiss based on preemption. The district court held (1) that Plaintiffs failed to plausibly allege that the Retailers and Defendants knew that ranitidine was misbranded, and (2) Plaintiffs' theory cannot apply to the Retailers and Distributors in any event. MDL.Dkt.2513 at 30. By failing to address these holdings, Plaintiffs have forfeited their challenge to the district court's order dismissing their claims against the Retailers and Distributors on preemption grounds.

Third, on the merits. Because the Retailers and Distributors had no ability under the FDCA to change the composition or labeling of ranitidine, the claims against them are preempted under *Bartlett* and *Mensing*. Plaintiffs' parallel misbranding theory—their sole strained attempt to avoid this straightforward result—is inconsistent with precedent and the FDCA's regulatory framework. The Court should reject Plaintiffs' theory and affirm the decisions below.

A. Plaintiffs' violation of this Court's briefing order forfeits their challenge to the district court's preemption rulings as to the Retailers and Distributors

In its December 26, 2023, consolidation order, this Court clearly specified that the "briefing as to the appellants with Rule 58 judgments in No. 21-12618, as referenced in the order dated October 18, 2023, shall remain separate from the

briefing of other appellants." CA11.Dkt.355-1 at 2. And the Court provided that the principal, consolidated brief that Plaintiffs would file in each appellate docket—that is, the Omnibus Brief that Plaintiffs filed as to the Retailers and Distributors and to which this brief responds—shall have a word limit of 28,000. *Id.* at 3. Moreover, the Court specifically permitted the parties to "incorporate by reference the consolidated briefing" in *one* set of briefing—the "briefing as to the appellants in no. 23-12742[,]" which "address[es] only the unique class-action-related issues…." *Id.* at 2.

Notwithstanding that order, the entirety of Plaintiffs' preemption argument as to the Retailers and Distributors in their Omnibus Brief consists of a single paragraph in which they purport to "incorporate … by reference" one of the arguments set forth in the "Generic-Only Appellants' opening brief[.]" Omnibus Br. at 27.[8] That separate Generics-Only brief was filed by a discrete group of 18 plaintiffs. CA11.Dkt.355-1 at 2. None of those plaintiffs made any claim against any of the Retailers or Distributors (or the Brands)—which, as noted, is why they obtained Rule 58 final judgments separate from, and much earlier than, all the other plaintiffs. *See id.*

Given that *some* grounds for decision in the district court's preemption orders in favor of the Generics overlap with those in favor of the Retailers and Distributors,

[8] Plaintiffs press their second set of arguments against preemption, *see* Generics-Only Br. at 44–57, *only* against the Generics and the Brands, *not* the Retailers and Distributors, Omnibus Br. at 27.

one might be tempted to dismiss Plaintiffs' "incorporation by reference" tactic as a merely technical violation of the Court's order requiring separate briefing. But it is not. This Court has long disapproved of efforts to circumvent word limit restrictions through "incorporation by reference." The Court has held that "Rule 28(i) does not permit adoption of arguments by reference between cases unless a motion for adoption is made and granted[.]" *United States v. Schultz*, 565 F.3d 1353, 1362 (11th Cir. 2009) (rejecting defendant's "attempt to adopt his codefendant's argument"); *cf. Four Seasons Hotels & Resorts, B.V. v. Consorcio Barr S.A.*, 377 F.3d 1164, 1167 n.4 (11th Cir. 2004) (rejecting "the practice of 'incorporating by reference' arguments made elsewhere" because the practice "makes a mockery of our rules governing page limitations and length").[9]

After all, it was *Plaintiffs* who insisted that the 18 plaintiffs involved in the Generics-only actions be treated separately on appeal. CA11.Dkt.346. The Court acquiesced and authorized a separate brief. CA11.Dkt.355-1. The Court then specified a 28,000-word limit for Plaintiffs' *Omnibus Brief*, *denying* Plaintiffs' request for 39,000 words. *Id.* at 3; *see Krause*, CA11 Appeal No. 23-13283, Dkt.104

[9] Whereas Plaintiffs' Omnibus Brief impermissibly purports to incorporate another party's brief in a *different* appellate docket, this brief incorporates another party's brief in the *same* appellate docket, as expressly authorized by Federal Rule of Appellate Procedure 28(i)—which provides that in "a case involving more than one appellant or appellee, including consolidated cases, … *any party may adopt by reference a part of another's brief*." (emphasis added).

at 7. Plaintiffs' incorporation-by-reference maneuver is an overt end-run around this limit. Plaintiffs' two briefs ultimately total 40,468 words, more than one thousand *more* words than they (unsuccessfully) requested: 27,970 for the Omnibus Brief and 12,498 words for the additional arguments set forth in the Generics-Only Brief and "incorporated by reference" in the Omnibus Brief. It would be one thing for the 18 plaintiffs in the Generics-Only case to incorporate by reference arguments in the Omnibus Brief, thus saving words and repetition. It is quite another for Plaintiffs filing the Omnibus Brief to use the Generics-Only Brief to stretch their own word limits from the 28,000 they were assigned to the 42,000 they have now taken for themselves.

This Court's briefing order identified *one* circumstance in which the parties could incorporate by reference, despite the direction for separate briefing: The parties' *class-action* briefs could incorporate the arguments in the consolidated, omnibus briefs. CA11.Dkt.355-1 at 2. This approach was designed to *reduce* repetition, and did *not* expand the number of words assigned to Plaintiffs for their Omnibus Brief. Class-action plaintiffs were directed to file a brief addressing "unique class-action-related issues[,]" and the Court permitted them to streamline their brief by incorporating the Omnibus Brief's merits arguments. *Id.*

The incorporation tactic Plaintiffs employed in their Omnibus Brief does just the opposite. It is an attempt to unilaterally expand the word limit established by the

Court. The Court should hold that Plaintiffs have "waived the arguments [they] ha[ve] not properly presented for review." *Four Seasons*, 377 F.3d at 1167 n.4.

B. By failing to challenge the district court's rulings, Plaintiffs have forfeited their parallel misbranding theory against the Retailers and Distributors

In addition to violating this Court's briefing order, Plaintiffs have forfeited their preemption argument as to the Retailers and Distributors because they fail to address the district court's independently sufficient grounds for finding preemption in favor of the Retailers and Distributors—not even in their inappropriately incorporated-by-reference Generics-Only Brief. Unsurprisingly, the Generics-Only Brief—filed by 18 plaintiffs who raised claims against only the Generics and not any retailer or distributor—addresses *only* the distinct district court order granting the *Generics'* motion to dismiss. *See* Generics-Only Br. at 12–14, 33–34, 41–42 (discussing MDL.Dkt.2512, the district court order dismissing claims against Generics). Indeed, the Generics-Only Brief does not discuss, even by way of background, the Retailers and Distributors, their arguments, or the specific and distinct bases upon which the district court rejected Plaintiffs' claims against them. The Generics-Only Brief refers to the district court order dismissing Plaintiffs' claims against the Retailers and Distributors only once, in a "see also" citation that incorrectly asserts this order provided the "same reasoning" as the preemption order regarding Generics. *Id.* at 43 (citing to MDL.Dkt.2513).

Plaintiffs' oversight is fatal, for the district court's order dismissing the claims against the Retailers and Distributors on preemption grounds only *partially* overlapped with its preemption order regarding the Generics. The only theory that Plaintiffs even arguably raise as to the Retailers and Distributors on appeal is the theory that "their claims are parallel to federal law" because they "have alleged that the Defendants sold misbranded drugs" under federal law. MDL.Dkt.2513 at 28. The district court's dismissal order as to the Retailers and Distributors set forth *four distinct reasons* for rejecting this theory. *Id.* at 30–32; *see supra* at 17–18. At least two of these reasons *are not among the reasons* the district court gave for dismissing Plaintiffs' claims against *Generics*—and are not addressed by Plaintiffs' Generics-Only Brief. These two grounds are thus left unchallenged on appeal. Consequently, Plaintiffs have forfeited their challenge to those grounds for decision, and the judgments for the Retailers and Distributors should be affirmed for this reason alone.

In particular, Plaintiffs base their defense of their parallel misbranding theory in this Court by asserting that, "[c]rucially," Generics-Only Br. at 13, "[u]nder the facts Appellants have alleged, and that the district court *assumed*, MDL.Dkt.2512 at 30, both state and federal law required Defendants to stop selling ranitidine[,]" *id.* at 33. That "assumption" was made *solely in connection with the district court's order concerning the Generics*. MDL.Dkt.2512 at 30 ("For the purpose of this Order,

the Court assumes, without finding, that Plaintiffs have adequately alleged that ranitidine products were misbranded.").

In contrast, as its first reason for rejecting Plaintiffs' misbranding theory asserted against the Retailers and Distributors, the district court actually *held* precisely the opposite. Rather than assume Plaintiffs adequately alleged that the Retailers and Distributors violated the FDCA, the district court held that "Plaintiffs *have not plausibly alleged* that the [Retailers and Distributors] *knew* that the drugs were misbranded or otherwise could have detected the alleged defects in the ranitidine molecule." MDL.Dkt.2513 at 30 (first emphasis added); *see also id.* (citing *In re Darvocet*, *Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 929–30 (6th Cir. 2014), discussed *infra* at 79–80, holding that defendant's *knowledge* of new, scientifically significant information of harm, not presented to the FDA at the time of approval, was a necessary element of a parallel misbranding theory). None of Plaintiffs' briefs confront this critical, dispositive holding.

Moreover, the district court's second reason for rejecting Plaintiffs' parallel misbranding theory was its holding that such a theory could possibly be viable only in connection with hypothetical "pure design-defect claims," which "could only be brought against a manufacturer—not a retailer or a distributor." MDL.Dkt.2513 at 30 (citing *In re Darvocet*, 756 F.3d at 929–30). This rationale does not apply to

the Generics (who of course *are* manufacturers), and Plaintiffs' Generics-Only Brief does not address it.

Accordingly, Plaintiffs' opening briefs do not challenge the legal or factual basis for either of these independently sufficient determinations. Plaintiffs have thus forfeited any such challenges. *See, e.g.*, *Thomas v. Bryant*, 614 F.3d 1288, 1314, n.24 (11th Cir. 2010) (objection to district court finding waived where appellants "have not challenged [the district court's finding], either in the district court or on appeal"); *N. Am. Med. Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211, 1217 n.4 (11th Cir. 2008) ("This circuit has consistently held that issues not raised on appeal are abandoned."); *Garvich v. Georgia*, No. 21-10679, 2022 WL 1531701, at *1 (11th Cir. May 16, 2022) ("An appellant also forfeits a claim when it is raised for the first time in his reply brief.") (citation omitted). Either of these rulings is sufficient to reject Plaintiffs' parallel misbranding theory—and is thus sufficient to affirm the district court's judgment for the Retailers and Distributors. This Court should do so.

C. The district court's preemption ruling is correct on the merits

The procedural grounds cited above are by themselves sufficient to sustain the district court's judgment for the Retailers and Distributors. And Plaintiffs' parallel misbranding theory—their sole argument against preemption—further fails on the merits.

The Supremacy Clause specifies that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Law of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2; *see also Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) ("any state law ... which interferes with or is contrary to federal law, must yield" (cleaned up)). In its many decisions applying this principle, the Supreme Court has held that state laws are preempted (1) if Congress has explicitly declared such laws preempted; (2) if Congress has reserved an entire field of regulation to the federal government; and (3) as here, if state and federal law conflict. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990).

A preemption-causing conflict exists either where "it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 79 (internal quotation marks and citation omitted); *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). And state requirements preempted by federal law include "common-law duties" under state tort law. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008). When federal law conflicts with such state-law duties—*e.g.*, when federal law prohibits the defendant from taking the actions the plaintiff claims state law required—the state-law duties are "without effect." *Altria*, 555 U.S. at 76 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

The Supreme Court has had several occasions to address how these principles apply in the context of the FDCA's rules regulating the pharmaceutical industry. Those cases have produced a straightforward rule that easily resolves this case: Where, as here, the FDCA "prohibit[s] [defendants] from unilaterally altering drug composition or labeling," the FDCA makes "it impossible … to comply with both state and federal requirements" and thereby preempts state-law tort claims against them. *Bartlett*, 570 U.S. at 490 (cleaned up).

1. *Mensing* and *Bartlett* squarely hold that the FDCA preempts state claims where the defendant cannot alter the drug's composition or label

Bartlett suffices to resolve this case. And the Supreme Court's series of cases leading up to that decision, which carefully examine the FDCA's provisions and constitutional preemption principles, demonstrate that *Bartlett*'s holding was built on a solid foundation and confirm its applicability here.

In *Wyeth*, the user of a brand-name drug sued the manufacturer—an NDA holder—on negligence and strict-liability theories, claiming that the manufacturer had marketed the drug with an inadequate warning. 555 U.S. at 559–60. The Supreme Court held that although the FDA had approved the manufacturer's NDA to market the drug, plaintiff's failure-to-warn claim could proceed because the FDCA allowed the NDA holder defendant to "unilaterally strengthen" the warning or change the label, subject to the FDA's subsequent disapproval. *Id.* at 573.

In contrast, in *Mensing*, the Court held that the FDCA preempted claims against *generic manufacturers* that are ANDA holders. The plaintiffs, like those in *Wyeth*, claimed that the defendants had failed to provide adequate warnings. 564 U.S. at 610. And the Court held that the FDCA preempted these claims because ANDA holders—*unlike* NDA holders—*cannot* "unilaterally strengthen their warning labels." *Id.* at 614; *see also id.* (accepting the FDA's interpretation of its regulations on this point).

Notably, in *Mensing*, the FDA, as amicus, argued against preemption. It pointed out that it is unlawful "misbranding" under the FDCA to market a drug unless its labeling bears warnings necessary to adequately protect users. *Id.* at 616 (citing 21 U.S.C. §352(f)(2)). Indeed, "[b]y regulation, the FDA has interpreted that statute to *require* that 'labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.'" *Id.* (emphasis added; quoting 21 C.F.R. §201.57(e) (now codified at 21 C.F.R. §201.80(e)). The FDA thus argued that under the FDCA generic manufacturers "*must* ask the agency to work toward strengthening the label[.]" *Id.* (emphasis added). And it insisted that plaintiffs could bring state-law claims against generic manufacturers if they failed to do so, on the theory that "[i]f the FDA had agreed that a label change was necessary, it would have worked with the brand-name manufacturer to create a new label for both the brand-name and generic drug." *Id.*

at 620; Brief for the United States as Amicus Curiae in Support of Respondents at 26, *PLIVA v. Mensing*, Case Nos. 09-993, 09-1039, and 09-1501 (U.S. Mar. 2011) (arguing that, "[w]hen, as here, federal law requires a manufacturer to act to update its labeling, a State may impose a similar duty and consequent damages liability for failing to meet that duty").

The Supreme Court rejected the FDA's theory. It held that even if the misbranding provisions required a generic manufacturer, upon learning of a deficiency, to propose a label change, the failure to fulfill that federal duty had no effect on the preemptive conflict between state and federal law—*i.e.*, that federal law foreclosed the defendant from unilaterally instituting a label change that would allow it to avoid liability under state law. *Id.* at 620–21. The Court explained that a preemption analysis that rested on what the FDA *might do* in the future—by approving a proposed label change—would eviscerate the historic conception of pre-emption: "If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force." *Id.* at 621. Refusing to "read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless," *id.*, the Court reiterated that the critical question "is whether the private party could independently do under federal law what state law requires of it," *id.* at 620 (citing *Wyeth*, 555 U.S. at 573).

The Court again underscored this point in *Bartlett*, its most recent treatment of these issues. There, the Court addressed a New Hampshire design-defect claim brought against a generic manufacturer, alleging a failure to ensure that the drug was reasonably safe. 570 U.S. at 475. Under New Hampshire law—and, as the Court observed, the law of most states, *id.* at 485, n.2—a manufacturer could satisfy its duty to ensure its drug was reasonably safe "either by changing a drug's design or by changing its labeling," *id.* at 482. As a matter of federal law, however, the generic manufacturer could neither make the drug "in another composition," *id.* at 484 (cleaned up), nor take "the remedial action required to avoid liability" by changing the labeling, *id.* at 486. It was thus "impossible for [the defendant] and other similarly situated manufacturers to comply with both state and federal law," which foreclosed the plaintiff's claim under straightforward conflict-preemption principles. *Id.* at 486–87.

The Court then turned to the theory on which the First Circuit had rejected preemption—that the generic manufacturer could have complied with *both* federal and state law simply by not selling the drug at all. *Id.* at 488. The Court flatly rejected the First Circuit's theory as incompatible with its longstanding preemption jurisprudence: "Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations *is not required to cease acting altogether in order to avoid liability*." *Id.* (emphasis added). "In every instance in which the Court

has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting." *Id.* And the Court cited *Mensing* as an example of an earlier case that had rejected the stop-selling theory *sub silentio*; after all, the plaintiff in *Mensing* "advanced the stop-selling rationale in its petition for rehearing, which this Court denied." *Id.* at 489. The Court thus rebutted the dissent—which contended that the possibility of ceasing sales meant it was "not 'literally impossible' … to comply with both state and federal law"—by observing that the dissent's position "would render impossibility pre-emption 'all but meaningless.'" *Id.* at 487 n.3 (quoting *Mensing*, 564 U.S. at 621).

2. Because the FDCA prohibited the Retailers and Distributors from altering the composition or labels of ranitidine products, *Mensing* and *Bartlett* require preemption here

Plaintiffs do not dispute that all their claims require them "to show that something was wrong with ranitidine's design or label[.]" MDL.Dkt.2513 at 23. Nor do Plaintiffs dispute that the Retailers and Distributors are "powerless to cure a design defect in a drug, to make changes to the drug's label, or to issue other warnings without FDA approval." *Id.* at 27. And rightly so, for the precedent establishing this point is overwhelming. *See, e.g.*, 21 U.S.C. §356a(c) (prohibiting changes to composition of approved drug); *Greager v. McNeil-PPC, Inc.*, 414 F. Supp. 3d 1137, 1143 (N.D. Ill. 2019) (holding design and failure-to-warn claims

preempted because "[i]t was impossible under federal law for defendants to do what plaintiff sues them for failing to do: alter the label or the composition of the product to better reflect or reduce the product's health risks"); *Smith v. Teva Pharms. USA, Inc.*, 437 F. Supp. 3d 1159, 1165–66 (S.D. Fla. 2020) ("The FDA's regulations nowhere contemplate a distributor of a brand drug, … initiating changes to an approved NDA.").[10]

Under *Mensing* and *Bartlett*, those concessions resolve this case, because these decisions hold that state law is preempted where "federal law prohibit[s] [the defendant] from taking the remedial action required to avoid liability under [state] law." *Bartlett*, 570 U.S. at 486. And they further hold that a plaintiff cannot avoid this result by insisting that the defendant "pull their products from the market

[10] *See also, e.g.*, *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298–99 (6th Cir. 2015) (holding plaintiff's "post-approval design defect claim is clearly preempted by federal law" because "federal law prohibited defendants from decreasing the dosage"); *Hernandez v. Aurobindo Pharma USA, Inc.*, 582 F. Supp. 3d 1192, 1210 (M.D. Fla. 2022) ("[A]ltering either the drug's label or design was impossible for CVS under federal law because CVS lacked the ability to do so."); *Brazil v. Janssen Rsch. & Dev. LLC*, 196 F. Supp. 3d 1351, 1364–65 (N.D. Ga. 2016) (holding claims preempted because a "distributor, even of a brand name drug," cannot change labeling); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL No. 2243, 2012 WL 181411, at *3 (D.N.J. Jan. 17, 2012) (noting that distributor had no power to alter the drug's labeling because "[t]hat power lies with the applicant who filed the [NDA]"); *Stevens v. Cmty. Health Care, Inc.*, No. ESCV200702080, 2011 WL 6379298, at *1 (Mass. Super. Ct. Oct. 5, 2011) (distributor "had no ability to change labeling or warnings" and thus could not be liable).

altogether." *Id.* at 488. For these reasons, federal courts consistently hold all types of tort claims preempted in such circumstances.[11] As the district court observed, "[i]n contrast to the foregoing authority, the Plaintiffs have provided *no citation* to a case where similar claims against retailers (or distributors) survived a pre-emption analysis." MDL.Dkt.2513 at 20 (emphasis added).

[11] *See, e.g.*, *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1248–1250 (11th Cir. 2013) (holding that claims for negligence, strict liability, breach of warranty, misrepresentation, fraud, and negligence per se were preempted under *Mensing*); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 680 (5th Cir. 2014) (*per curiam*) ("[P]recedent makes clear that [plaintiff's] breach of warranty claims are preempted, and thus meritless."); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474–75 (5th Cir. 2014) (holding claims preempted because "the duty of sameness prohibits the generic manufacturers from taking [actions] unilaterally, they are dependent on brand-names taking the lead") (internal citation and quotation marks omitted); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 477 (4th Cir. 2014) (holding claims for negligence, breach of warranty, misrepresentation, strict liability, and failure to warn were preempted because generic manufacturer "could not satisfy [its state law] duty without changing its warnings, changing its formulation, exiting the market, or accepting tort liability"); *In re Darvocet*, 756 F.3d 917 (holding claims for failure-to-warn, design defect, breach of express and implied warranty, fraud, misrepresentation, breach of consumer protection statutes, and unjust enrichment claims were preempted); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) ("Because no brand-name manufacturer sent a warning … the generic manufacturers were not at liberty to do so. As *Mensing* concluded, preemption is thus triggered[.]"); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1288 (10th Cir. 2013) (holding claims preempted because plaintiffs did not identify a mechanism through which the manufacturer "could have modified or supplemented the warranties allegedly breached without running afoul of the duty of sameness").

3. *Mensing* and *Bartlett* foreclose Plaintiffs' parallel misbranding theory

With every relevant FDCA preemption case against them, Plaintiffs offer a novel theory by which they seek to evade preemption. They insist their state-law claims "parallel the federal misbranding statute" on the ground that "the FDCA and state law required the Generic Defendants to withdraw their drugs from the market because they were unsafe." Generics-Only Br. at 28 (cleaned up). That theory, however, is ultimately only a repackaging of the "stop-selling" rationale that *Mensing* and *Bartlett* have already repudiated. Plaintiffs' parallel misbranding theory flouts these decisions and "would render impossibility pre-emption a dead letter[.]" *Bartlett*, 570 U.S. at 475. This Court should reject it.

Plaintiffs' reference to misbranding adds nothing to the argument the Court rejected in *Bartlett*. Consider the state-law duties Plaintiffs invoke. Plaintiffs do not contest that all their claims rest on the allegation that ranitidine is unreasonably dangerous in light of its benefits and potential harms, which are judged in light of the products' warnings and instructions. MDL.Dkt.2513 at 25–26; *accord* Generics-Only Br. at 36–37. That is the same *Restatement (Second) of Torts* §402A comment k framework underlying the claims in *Bartlett*. 570 U.S. at 485 n.2. Plaintiffs ultimately rest their description of state-law duties on the broad premise that "every state would allow a company to comply with state law by withdrawing the drug from the market." Generics-Only Br. at 36–37. And this is the very same premise *Bartlett*

addressed in *rejecting* "not selling" as a way to avoid preemption. 570 U.S. at 475 (rejecting notion that defendant "should simply have pulled [the drug] from the market in order to comply with both state and federal law").

As for federal law, the misbranding provisions prohibit the sale of drugs where the *existing* instructions are misleading or fail to mitigate the danger. The FDCA identifies various forms of misbranding, including selling or receiving a product with false or misleading labels, or selling or receiving a product "dangerous to health" notwithstanding accompanying warnings and instructions. 21 U.S.C. §352(a)(1), (f), (j); *see also* 21 U.S.C. §331(a). And the FDA may, upon notice and hearing, withdraw approval for a misbranded drug,[12] or take any number of remedial actions to seize or enjoin, or (subject to certain exceptions) even penalize the sale of misbranded drugs. *See* 21 U.S.C. §§332, 333, 334.[13]

Plaintiffs thus insist that both state and federal law impose a "duty not to sell unreasonably dangerous products"—a duty that might in theory be met either by changing a product's composition or label, or by not selling it at all. Generics-Only Br. at 33. That was the same choice the manufacturer faced in *Bartlett*, *Mensing*, and

[12] The FDCA provides that FDA shall withdraw approval of a drug if, *inter alia*, it finds that the drug is not safe for the uses identified at the time of the drug's approval. 21 U.S.C. §355(e). Approval may be withdrawn only if the FDA affords the manufacturer the opportunity for a hearing. *Id.*

[13] The FDCA's misbranding provisions say nothing about barring sales of a particular drug entirely.

Wyeth. But changing the warnings or instructions was not an option that federal law made available to the manufacturers in *Bartlett* and *Mensing*, and it is not available to the Retailers and Distributors here. And the "stop-selling" option, always available to any market participant in theory, was squarely *rejected* as a means of reconciling state and federal law because it is "incompatible with [the Court's] pre-emption jurisprudence." *Bartlett*, 570 U.S. at 488.

Plaintiffs' argument is thus flatly inconsistent with *Mensing* and *Bartlett*. Whatever theoretical parallels may exist between certain aspects of state and federal law, the specific and determinative conflict remains: Federal law barred the Retailers and Distributors from avoiding state law liability by changing the composition, or the labeling, of the ranitidine they sold. As a result, lower courts have *uniformly rejected* Plaintiffs' parallel-misbranding theory as a way to avoid preemption of drug-defect claims. *See, e.g.*, *In re Darvocet*, 756 F.3d at 936 n.5 (holding that "Plaintiffs' misbranding theory fails in its entirety"); MDL.Dkt.2513 at 30 (noting "Plaintiffs have provided no authority" for their position).[14]

[14] *See also, e.g.*, *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 607 (N.D. Miss. 2013) (rejecting argument that *Mensing* did not apply to a claim that a manufacturer distributed a misbranded drug; "no matter how Plaintiff styles her theories of recovery, her claims ultimately relate to the Generic Defendants' alleged failure to warn"); *Moretti v. PLIVA, Inc.*, No. 08-CV-396, 2012 WL 628502, at *5 (D. Nev. Feb. 27, 2012) (rejecting argument that *Mensing* did not foreclose liability based on a generic manufacturer distributing a misbranded drug), *aff'd sub nom.*, *Moretti v. Wyeth, Inc.*, 579 F. App'x 563 (9th Cir. 2014); *Moretti v. Mut. Pharm. Co.*, 852 F. Supp. 2d 1114, 1118 (D. Minn. 2012) (court "not persuaded" by attempt to

Both *Mensing* and *Bartlett* evaluated the existence of a conflict between state and federal law by focusing on the actions the defendants could take to "render[] [their products] reasonably safe"—*i.e.*, either fix the products or change their instructions and warnings. *Bartlett*, 570 U.S. at 488; *see also Mensing*, 564 U.S. at 618 ("If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law."). *That* is the dispositive question. And here, there is no dispute that federal law prohibited the Retailers and Distributors from taking any action that would have made ranitidine "reasonably safe" to sell under state law.

Further, the Supreme Court has specifically rejected the argument that federal and state law do not conflict where it is "possible for [defendants] to pull their products from the market altogether." *Bartlett*, 570 U.S. at 488 (citing *Mensing*, 564 U.S. at 618–19). The Court's ultimate holding was, therefore, unequivocal: "[W]e hold that state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from

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differentiate misbranding from the claims addressed in *Mensing*), *aff'd*, 518 F. App'x 486 (8th Cir. 2013); *Metz v. Wyeth, LLC*, No. 10-CV-2658, 2011 WL 5024448, at *4 (M.D. Fla. Oct. 20, 2011) (misbranding claim fell "directly within the scope of *Mensing* because it [was] based on Actavis' purported failure to provide an adequate label and package insert"), *aff'd on other grounds*, 525 F. App'x 893 (11th Cir. 2013) (explaining that *Bartlett* and *Guarino* "disposed of all the claims before [the Court], including [plaintiffs'] negligent design claim").

unilaterally altering drug composition or labeling." *Id.* at 490. The same conflict exists here. Whatever actions the FDA may or may not take under the misbranding provisions, the conflict between state tort law and the Retailers and Distributors' inability to change the product or the instructions remains.

Plaintiffs' theory would thus eviscerate both *Bartlett* and *Mensing*, *and* the reasoning of *Wyeth*, where the Court declined to find preemption based on the defendant's unilateral ability to change the drug label. *Wyeth*, 555 U.S. at 573. That issue need not have been reached if "not selling" eliminated the apparent conflict between the demands of state and federal law.

Indeed, Plaintiffs scarcely make any effort to cabin the consequences of their theory. The FDCA misbranding provision that Plaintiffs invoke deems a drug misbranded "[i]f it is *dangerous to health* when used in the dosage or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. §352(j) (emphasis added). Of course, the plaintiffs in nearly *any* drug-defect case can argue—and the plaintiffs in *all* of these Supreme Court cases *did* argue—that the drugs at issue were dangerous to health when used in accordance with the drug labels. *See Wyeth*, 555 U.S. at 560 (gangrene); *Mensing*, 564 U.S. at 610 (tardive dyskinesia); *Bartlett*, 570 U.S. at 478 (toxic epidermal necrolysis). All these plaintiffs thus could have argued—and some *did* argue—that the drugs were

therefore misbranded under federal law and that there was therefore no conflict in imposing state-law liability for selling them.

Moreover, in rendering these decisions, the Supreme Court was well aware of the misbranding provisions. In *Mensing*, for example, it observed that the Government relied on the misbranding provisions to argue that a generic manufacturer, faced with new information, should propose a labeling change. 564 U.S. at 616, 619. The Court rejected that argument because it would embroil the preemption analysis in speculation about what the FDA *might* do if presented with certain facts, rather than what the FDA had actually done and how federal law stood at the relevant time. *Id.* at 620–21.

In fact, *Bartlett* reasoned that *Mensing*, though it did not specifically discuss "stop-selling" arguments, *implicitly rejected them*. *Bartlett*, 570 U.S. at 488–90. To confirm this point, *Bartlett* explicitly relied on the rehearing petition in *Mensing*, which raised a stop-selling argument that precisely mirrors Plaintiffs' misbranding argument here:

> Federal law prohibits the sale of misbranded drugs, 21 U.S.C. §331, and deems a drug to be misbranded if it lacks "adequate warnings." 21 U.S.C. § 352(f)(2). Thus, Respondents' state law failure-to-warn claims "parallel" the duties imposed on drug manufacturers under federal law.

PLIVA, Inc. v. Mensing, Resp'ts' Pet. for Reh'g, No. 09-993, 2011 WL 2874547, at *3 (U.S. July 18, 2011) (cited in *Bartlett*, 570 U.S. at 489).

In short, the Court in *Mensing* and *Bartlett* recognized the misbranding provisions and did not view them as obviating the conflict between state and federal law with which the Court was concerned. Federal law prohibited the defendant from taking steps, such as by changing the composition of the drug or its labeling, to avoid the liability state law would impose, and the Court rejected the only other alternative—not selling the drug at issue—as "no solution" to conflict preemption. *Bartlett*, 570 U.S. at 475.

a. Footnotes 3 and 4 of *Bartlett* do not change its holding

Faced with the Supreme Court's clear-as-day holdings, Plaintiffs invoke two footnotes in *Bartlett*—footnote 3, which referred to "the rare case in which state or federal law actually requires a product to be pulled from the market," 570 U.S. at 487 n.3, and footnote 4, which noted that "[w]e do not address state design-defect claims that parallel the federal misbranding statute," *id.* at 487, n.4. Invoking these footnotes, Plaintiffs contend that this Court can disregard the holding and implications of *Bartlett* because "[w]hen the Supreme Court says it is not deciding a question, it necessarily believes that the question held open *is not controlled by its holding*." Generics-Only Br. at 40 (emphasis added).

That is incorrect. When the Supreme Court says it is not *addressing* a question, it means it is not *considering* whether the question is controlled by its holding or other aspects of its decisions—in that case or in prior cases. Such

statements do *not* mean that the question is open to the lower courts to start afresh. In this case, as in any other, the lower courts are bound to consider the implications of the Supreme Court's holdings and reasoning on the issues presented.

Plaintiffs' parallel misbranding theory would nullify the Supreme Court's holdings in a series of well-considered opinions addressed to this same, specific area of law. As the district court noted—in a conclusion Plaintiffs do not dispute on appeal—nothing distinguishes Plaintiffs' case from any other: "If Plaintiffs' position were accepted, a plaintiff could avoid pre-emption simply by asserting, for example, that a drug's labeling was 'false or misleading in any particular' or that the drug was 'dangerous to health when used' as prescribed." MDL.Dkt.2512 at 28 (quoting 21 U.S.C. §352(a)(1), (j)). Plaintiffs' theory would thus "render pre-emption caselaw meaningless." *Id.* That is reason enough to reject it.

For their part, Plaintiffs propose to distinguish *Bartlett*'s clear holding by arguing that it applies only where "stop selling" is merely an "option"—whereas here, Plaintiffs maintain, "the FDCA *prohibited* Defendants from selling ranitidine…." Generics-Only Br. at 39–40. Notably, this distinction *does not distinguish Plaintiffs from every other plaintiff claiming personal injuries from an FDA-approved drug*. Every such plaintiff could argue, as Plaintiffs do here, that the drug they took was dangerous to health and that the FDCA thus made it illegal to sell.

Regardless—and setting aside the decisive fact that the FDCA's "bar" on sales of misbranded drugs is implemented prospectively though FDA regulatory enforcement actions, which never occurred for ranitidine products—Plaintiffs' proposed distinction is legally irrelevant. In either case, federal law bars defendants from taking the action that Plaintiffs claim is necessary to render the product lawful to sell under state law.[15] Indeed, *Bartlett* specifically addressed this supposed distinction between an option and compulsion to stop selling and rejected it as "purely semantic." 570 U.S. at 489, n.5 (rejecting plaintiff's attempt to distinguish *Mensing* and explaining that "an affirmative duty … to improve the product's label … could just as easily have been phrased as a duty not to sell the drug without adequate warnings" (cleaned up)).

At bottom, Plaintiffs' misbranding theory is irreconcilable with *Mensing* and *Bartlett*—not to mention the scores of lower-court decisions that have found FDCA preemption in cases in every relevant respect identical to these actions.

b. Plaintiffs do not meet the elements of their own parallel misbranding theory

Equally fatal to their argument, Plaintiffs' allegations do not fit within the "design-defect claims that parallel the federal misbranding statute" on which *Bartlett*

[15] Plaintiffs also mention the FDA's voluntary market withdrawal letter, but they do not explain how that letter is relevant to their parallel misbranding theory—much less how it could possibly distinguish their actions from every other mine-run drug-defect case. *See* Generics-Only Br. at 35.

reserved decision. *Id.* at 487 n.4. In its brief discussion on this point—including in the very next sentence—the Court repeatedly refers to a hypothetical drug that the FDCA might "require[] a manufacturer to pull … from the market[.]" *Id.*; *see also id.* at 487 n.3. That suggests the Court was contemplating a drug that was already the subject of an FDA injunction or seizure action. *See* 21 U.S.C. §§331(a)–(c), (g), and (k); 21 C.F.R. §314.170; 50 Fed. Reg. 7452, 7488 (Feb. 22, 1985) (reserving right to use misbranding provisions as basis for injunctions or seizure without first withdrawing approval). After all, if a manufacturer fails to comply with an FDA order to withdraw a drug, there is a much stronger basis upon which to argue that state and federal law are "parallel." That is not the circumstance here.

Further, as the Sixth Circuit held *In re Darvocet*, *if* a plaintiff can *ever* evade FDCA preemption under a "parallel misbranding" theory, "Footnote 4 of *Bartlett* indicate[s that] the minimum that a plaintiff must show" includes establishing that there was "'new and scientifically significant information' that the [defendants] possessed that was not before the FDA." 756 F.3d at 929–30 (quoting *Bartlett*, 570 U.S. at 487 n.4); *accord* MDL.Dkt.2513 at 30 (citing *In re Darvocet*, 756 F.3d at 917). Yet Plaintiffs *do not argue that the Retailers and Distributors possessed any new and scientifically significant information*. Indeed, they do not address the Retailers and Distributors at all. Their "parallel misbranding theory" thus fails on this ground as well.

As the Sixth Circuit explained, 756 F.3d at 929, footnote 4 of *Bartlett* is based on the amicus brief the United States filed in that case, which raised the hypothetical possibility that state law might create liability for a "'pure' design-defect claim that does not consider the adequacy of labeling," *Mut. Pharm. Co. v. Bartlett*, U.S. Amicus Br., No. 12-142, 2013 WL 314460, at *12 (U.S. Jan. 22, 2013). The United States expressed no doubt that under *Mensing*, if state law allows for a label change to mitigate risk, and federal law forbids it, that conflict requires preemption, and there is no route around that holding based on a "stop selling" theory.[16] The United States' reservation addressed only a hypothetical circumstance where a State recognizes a "pure design defect theory" under which instructions and warnings are not "considered," so the precise holding of *Mensing* (which focuses on labelling), would not have applied. *Id.* at *20. That is not this case. In fact, the United States noted that "[i]t does not appear that this approach has been accepted in the States to any significant degree," and it did not identify *any* state that employs such an approach. *Id.*; *see also* MDL.Dkt.1976 at 14 (Plaintiffs asserting "there is no such thing as a 'pure'… design-defect claim").

[16] The United States explained that a "not selling" theory could "not be squared with *Mensing*, which reflects an implicit judgment that the option of withdrawing from a market is not sufficient to defeat impossibility preemption in this context." *Bartlett,* U.S. Amicus Br., 2013 WL 314460, at *12.

Moreover, the United States concluded that even if a state were to authorize "pure" design-defect claims, such "claims would be preempted where state law does not require the plaintiff to prove that the manufacturer *knew or should have known of new and scientifically significant evidence that rendered the drug misbranded under federal law*." *Id.* at 22 (emphasis added). This is the source of *Bartlett* footnote 4's reference to "new and scientifically significant information" (a phrase that does not appear in the FDCA's misbranding provision).

Plaintiffs cannot apply this theory to the Retailers and Distributors; indeed, they do not attempt to do so. After all, the Retailers and Distributors are not manufacturers, do not design drugs, and do not monitor or report on adverse events associated with the drug's use. *See* 21 C.F.R. §§314.80, 314.81, 314.98. And the district court determined that "Plaintiffs have not plausibly alleged that [the Retailers and Distributors] *knew* that the drugs were misbranded or otherwise could have detected the alleged defects[.]" MDL.Dkt.2513 at 30. Plaintiffs do not challenge this conclusion and disclaimed any allegation of actual knowledge or duty to know in any event. MDL.Dkt.3683 at 88:11-89:4.

Accordingly, Plaintiffs' claims against the Retailers and Distributors do not meet any theory on which the Supreme Court could be said to have reserved decision in *Bartlett*. The Court should therefore affirm the district court's preemption ruling.

c. The express preemption cases that Plaintiffs cite do not support their parallel misbranding theory

As demonstrated above, the FDCA's misbranding provisions provide no basis upon which to avoid the clear holdings and reasoning of *Bartlett* and *Mensing*. Plaintiffs therefore propose a different form of analysis, which they insist turns on whether there are "any state common-law duties that 'parallel' federal requirements…." Generics-Only Br. at 30.[17] Yet Plaintiffs offer no precedent to support the use of such analysis to resolve a constitutional *conflict* preemption case, let alone for supplanting the detailed conflict-preemption analysis that the Supreme Court has repeatedly employed, and found decisive, in addressing the particular statutory framework here (the FDCA).

[17] To lend credence to their theory, Plaintiffs purport to source it in opinions by Justice Thomas suggesting that an "originalist reading" of the Supremacy Clause requires an implied repeal *non obstante* analysis. Generics-Only Br. at 33 (citing *Mensing*, 564 U.S. at 621 (plurality op.); *Wyeth*, 555 U.S. at 590 (Thomas, J., concurring)). Plaintiffs do not explain, however, how that theory would win for them here, where any arguable parallelism between state and federal law in one respect would not cure the clear conflict between state and federal law—as recognized by Supreme Court precedent—in another. Indeed, as Justice Thomas explained, under a *non obstante* analysis "courts should not strain to find ways to reconcile federal law with seemingly conflicting state law." *Mensing*, 564 U.S. at 622 (plurality). Regardless, the Supreme Court has never endorsed the implied repeal approach: Justice Thomas wrote for himself in *Wyeth*, and a majority of justices declined to join the portion of his *Mensing* opinion that discussed that theory. Indeed, the fact that the remainder of Justice Thomas's opinion in *Mensing* (which was for the Court) applied existing doctrine—and that Justice Thomas joined the majority opinion in *Bartlett*—demonstrates that those decisions are consistent with his approach.

To the contrary, Plaintiffs rely entirely on cases that both address significantly different regulatory frameworks and involve the very different analysis that arises from the interpretation and application of certain *express* preemption provisions. *See id.* at 29–30, 33–34. These cases offer no support for Plaintiffs' position.

Express preemption cases are essentially exercises in statutory interpretation. As this Court has recently observed, express preemption cases "turn[] primarily on the language of the preemption statute and the statutory framework surrounding it." *Carson v. Monsanto Co.*, 92 F.4th 980, 989 (11th Cir. 2024) (internal quotation marks and citation omitted). All of the cases that Plaintiffs cite involve unrelated statutory provisions whose meaning sheds little light on the preemption question here. *See id.* (interpreting express preemption provision of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447–48 (2005) (same); *Riegel*, 552 U.S. at 330 (interpreting express preemption provision of the Medical Device Amendments to the FDCA, which do not apply to drugs); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (same). Plaintiffs' argument is, therefore, off base.

As *Mensing* and *Bartlett* well illustrate, under the FDCA, conflict preemption analysis generally focuses on the concrete actions a defendant might take to avoid state tort liability. It also incorporates longstanding presuppositions of Supremacy Clause jurisprudence, which caused the Court (1) in *Mensing* to reject the possibility

that future agency action (approving a change to warnings) could reconcile state and federal law, 564 U.S. at 623–24, and (2) in *Bartlett* to reject "stop-selling" as a way to avoid the conflict between state and federal law, 570 U.S. at 488. There is simply no support for the notion that Plaintiffs' proposed approach could properly displace the kind of specific conflict found determinative in *Mensing* and *Bartlett,* let alone that it would do so in the context of the FDCA.

In *Carson*, this Court emphasized that even when addressing express preemption provisions, courts should not transpose the preemption analysis performed under one regulatory framework to a case involving a different regulatory framework: "[D]ifferent federal statutes and regulations may ... lead to different preemption results." 92 F.4th at 995 (quoting *Mensing*, 564 U.S. at 626); *see id.* (contrasting FIFRA's "relatively decentralized scheme" with the "decidedly centralized" FDA-driven framework imposed by the Medical Device Amendments). As noted, *none* of the cited cases deal with the provisions of the FDCA at issue here.

Further, *Carson* shows that the required analysis under express-preemption provisions is distinct from the analysis applicable to implied conflict preemption. *Compare Carson*, 92 F.4th at 989–96 (applying express preemption analysis) *with id.* at 996–99 (applying different analysis to potential conflict preemption question); *see also Carson v. Monsanto Co.*, 72 F.4th 1261, 1267 (11th Cir. 2023) (*en banc*) (rejecting argument concerning express preemption because it "relie[d] on

inapposite implied-preemption decisions"); *Jacob v. Mentor Worldwide, LLC*, 40 F.4th 1329, 1335–39 (11th Cir. 2022) (separating express preemption analysis from implied preemption analysis); *Lashley*, 750 F.3d at 476 (holding that inquiry mandated by express preemption provisions does not apply in conflict-preemption cases).

Indeed, *Carson* illustrates that specific federal requirements inconsistent with state-law duties will preempt state law, even where state and federal law could be said, at a higher level of generality, to pursue "parallel" purposes. In *Carson*, this Court concluded that FIFRA's express-preemption provision did not preempt the plaintiffs' failure-to-warn claim because "the practical effect" of both FIFRA and Georgia common law was the same—both "require pesticide manufacturers to warn users of potential risks to health and safety." 92 F.4th at 992. But the Court contrasted FIFRA's "general standards" (and approval process that "serves as only 'prima facie evidence' that the pesticide complies with FIFRA's requirements") with the specific mandates of the Medical Device Amendments that the Supreme Court addressed in *Riegel*—which are premised upon "a 'rigorous' conclusion that a device is safe and effective," and under which "manufacturers cannot change a device's label (or design, etc.) without the FDA's permission." *Carson*, 92 F.4th at 994–95.

Carson thus leaves no doubt that even in connection with express preemption provisions, and even if state and federal law might be characterized as parallel in some respects, state law is preempted where there are specific, practical conflicts between state-law requirements and federal-law requirements (*e.g.*, requirements in the FDA's approval of a medical device). And *Carson* says nothing about evading preemption via the notion that both state and federal law could be satisfied if the defendant left the market—the contention directly rejected in *Bartlett*.[18]

In sum, Plaintiffs' express preemption cases are inapposite and provide no basis to disregard the clear, on-point holdings of *Mensing* and *Bartlett*. The district court thus correctly held that Plaintiffs' claims are preempted because Retailers and Distributors "could not correct the alleged misbranding by altering the composition of the drug" or "alter[ing] the drug's label." MDL.Dkt.2513 at 30.

4. Plaintiffs' parallel misbranding theory also fails because it is inconsistent with the FDCA's regulatory framework

In addition to the points raised above, Plaintiffs' parallel misbranding argument fails on its own terms, for it misrepresents both the actual workings of the FDCA and the actions the FDA took. The FDCA gives the FDA considerable

[18] *Bartlett* likewise evaluated the conflict practically, based on the conventional options available to a company whose drug is alleged to be unsafe—either change the product, or change the warnings and instructions to render it safe. *See* 570 U.S. at 488–90. Under Plaintiffs' approach, in contrast, it is hard to see how *Bartlett* could have held the state claims preempted, because in *Bartlett* both state and federal law clearly allowed a party to avoid liability by not selling the product at issue. *See id.*

policymaking and enforcement discretion, and the FDA has *not* exercised that discretion to determine that ranitidine was misbranded. Plaintiffs thus lack the asserted predicate for their parallel misbranding theory.

a. Whether federal law is "parallel" cannot be judged without considering the FDA's actions

The FDCA's misbranding provisions—particularly 21 U.S.C. §352(j)'s prohibition on selling drugs that are dangerous when used in the manner recommended by their label—are applied in accordance with the FDA's highly discretionary judgments, which the FDA typically applies on a prospective basis. The penalty provisions are part of that discretionary framework, applied to downstream entities (such as the Retailers and Distributors) only where good faith is lacking.

Plaintiffs emphasize that the FDA has specified by regulation that the misbranding provisions apply even to approved drugs. Generics-Only Br. at 24. But the regulation Plaintiffs cite, 21 C.F.R. §314.170, merely preserves the *FDA*'s *own* broad authority to regulate, on an ongoing basis, drugs that it has previously approved, including by enforcing the misbranding provisions. And the provisions of the Federal Register cited by Plaintiffs, 50 Fed. Reg. at 7488, confirm that the regulation preserves the *FDA*'s ongoing authority to monitor and protect the public with respect to previously authorized drugs. After all, under the FDCA, the FDA is

both the exclusive approver of new drugs and the exclusive enforcer of the misbranding provisions.

In particular, the FDCA explicitly provides that the federal government has sole authority for enforcement—whether for injunction (21 U.S.C. §332), seizure (21 U.S.C. §334), or penalties (21 U.S.C. §§333 and 335)—of the FDCA. 21 U.S.C. §337(a) (providing that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"). This provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with FDCA requirements. *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). And as the Supreme Court has long recognized, the FDCA's "enforcement provisions ... commit complete discretion to the Secretary to decide how and when they should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). It is difficult to imagine a more obvious situation requiring the exercise of agency discretion than the decision whether to pursue a claim that an FDA-approved drug should be deemed dangerous and pulled from the market.

The result is that the misbranding sections are subject to the agency's considerable discretion. *See* 21 U.S.C. §§321(n); 331(a)–(c), (k); 352(a), (f), (j), (n). Contrary to Plaintiffs' contentions, unless and until the FDA takes prospective action

under one of the misbranding provisions, it cannot be said that the FDA imposes a "federal duty not to sell[.]" Generics-Only Br. at 34.

Further, both *Wyeth and Mensing* hold that FDCA preemption is to be judged on the basis of existing laws and restrictions, not speculation about what the agency might do. *Mensing*, 564 U.S. at 620–21; *Wyeth*, 555 U.S. at 573; *see generally Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019) (whether the FDA would reject a label change is a question of law requiring evidence that the FDA actually declined to approve the proposed change). Accordingly, the possibility that the FDA might seize or enjoin sales under the misbranding provisions cannot be the basis for avoiding preemption—especially where, as here, the defendant was prohibited from altering the drug's label or composition in a manner that would allow them to avoid liability.

b. Plaintiffs mischaracterize the FDA's actions

Plaintiffs know that their parallel misbranding theory would be more plausible—though still wrong—if the FDA had actually directed that ranitidine be seized or enjoined from further sales, or even if it had determined that it was misbranded. The FDA, however, has *not* determined that ranitidine was misbranded, let alone procured a court judgment or administrative order to remove ranitidine from the market.

Nonetheless, Plaintiffs sprinkle their Generics-Only brief with passing assertions that the FDA "*ordered* that all ranitidine be withdrawn from the market", Generics-Only Br. at 1, that the FDA "*compelled* Defendants ... to cease all ranitidine sales[,]" *id.* at 2, "*pulled* ranitidine because of its danger to health" from the market, *id.* at 35, or "*ordered* a recall[,]" *id.* at 36, and, most egregiously, that the "FDA *concluded*" "selling [ranitidine is] illegal under federal law[,]" *id.* at 35 (emphases added).

On the contrary, as Plaintiffs acknowledge elsewhere, the FDA "requested" a "voluntary" market withdrawal. *Id.* at 6, 35; *see also* Letter of Janet Woodcock, U.S. Food & Drug Admin., Dkt. No. FDA-2020-P-0042 at 10 (Apr. 1, 2020). This request in April 2020—which all Defendants abided by—provides no reason to allow Plaintiffs to evade preemption for claims arising out of sales that occurred in the preceding years. Indeed, the fact that the FDA exercises regulatory authority in such informal, discretionary ways underscores why a preemption analysis cannot properly be based on such informal actions—and assuredly cannot override the clear holdings of *Mensing* and *Bartlett*. *Cf. Buckman*, 531 U.S. at 353 (rejecting state tort claim premised on an effort to prove that the FDA had not been informed or had been misled).

c. The penalty provisions do not aid Plaintiffs' theory, especially as to Retailers and Distributors

Finally, while Plaintiffs insist that parties are subject to penalties under the misbranding provisions without proof of scienter, Generics-Only Br. at 10–11, they cite *no case* in which these provisions have actually been applied to a company or person that sold an FDA-approved drug with the label and composition required by the FDA.

Just as are the other enforcement provisions, the penalty provisions are subject to the control and discretion of the FDA. *See Heckler*, 470 U.S. at 831. And, of course, if the FDA decides to proceed in court, it will have to act in conjunction with the Department of Justice, since FDA lacks independent litigating authority. *Id.* at 835; *see also* CRS Report, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues* ("CRS Report") at 5 (Feb. 9, 2018).[19]

Notably, the FDA will not initiate a federal prosecution except after notice and an opportunity for the company to present its case. *See* 21 C.F.R. §7.84(a); CRS Report at 17. Thus, the penalty provisions associated with misbranding are not some form of self-executing restriction independent of the highly discretionary federal regulatory framework, but rather a fundamental part of a regulatory framework centered on obtaining cooperation from entities marketing approved drugs. And, as

[19] https://crsreports.congress.gov/product/pdf/R/R43609.

a matter of discretion, one would expect the FDA to proceed with greatest caution before seeking penalties against a party that sold an FDA-approved drug with the labeling and composition that the FDA had authorized.

In any event, the FDCA's penalty provisions do *not* contemplate strict liability for downstream purchasers and sellers. "No person" is subject to penalties for violating 21 U.S.C. §331, the misbranding provisions, "for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request … the name and address of the person from whom he purchased or received" the article in commerce, 21 U.S.C. §333(c). This exception reflects Congress' determination that downstream parties, while reasonably subject to prospective orders from the FDA, should not be subject to the same sorts of duties and liabilities that the FDCA imposes on manufacturers.

Decisively, Plaintiffs *do not allege* that Retailers and Distributors had, or could have had, any knowledge of the alleged defect in the ranitidine. Plaintiffs conceded that:

> With respect to a retailer, they are not in any position to know if the product is defective, that is particularly so for prescription drugs. Unlike a manufacturer who, acting even above a negligent standard of care could have certainly caught that their product was defective, there is nothing a retailer or distributor could do to make that same sort of catch. *So, there is no duty that they breached that they could have complied with.*

MDL.Dkt.2499 at 107:19–108:5 (emphasis added); *accord* MDL.Dkt.3683 at 88:11-89:4. Accordingly, as respects the Retailers and Distributors, Plaintiffs' reliance on the penalty provisions leads nowhere.

* * *

In sum, Plaintiffs' effort to avoid preemption of their claims against the Retailers and Distributors fails because they have presented no viable route around the clear and controlling holdings of *Bartlett* and *Mensing*. The statutory provisions they cite do not undermine the specific holdings and logic of those decisions; their allegations do not fit within the footnoted "exceptions" that Plaintiffs postulate; and the express-preemption cases on which Plaintiffs rely are wholly inapposite. For these reasons, the Court should affirm on preemption grounds the district court's judgments in favor of the Retailers and Distributors.

III. The District Court Properly Granted Judgment to the Retailers and Distributors Due to Plaintiffs' Failure, Individually and Collectively, to Show That Ranitidine Caused Their Injuries

While the district court's preemption ruling alone suffices to affirm the judgments in favor of the Retailers and Distributors, Plaintiffs' failure to adduce any admissible expert evidence in support of their claims separately justifies affirmance—and does so with respect to *every* Plaintiff. Plaintiffs quibble with the Rule 56(f) show-cause process that the district court used to determine to which parties it should apply its summary judgment ruling, Omnibus Br. at 78–84, but their

complaints are meritless. The summary judgment ruling thus provides an additional independent ground on which the Court should affirm.[20]

While Plaintiffs complain generally about the show-cause process, their actual due process argument is specifically limited to whether the show-cause process violated the due process rights of "later-filed plaintiffs who never agreed to use the experts the court had excluded[.]" Omnibus Br. at 10. This is confirmed by the very first sentence of Plaintiffs' due process argument, which asks the Court to "vacate the judgment against the many [Plaintiffs] who filed claims *after* the district court's Rule 702 order and never had any opportunity to contest general causation with their own experts and record." *Id.* at 78.[21] Accordingly, Plaintiffs have foregone any other challenge to the show-cause process, including the application of the summary judgment ruling to the Retailers and Distributors—notwithstanding their lone, citation-less assertion that they "told this Court in motions' practice[] the district court lacked authority to add a new ground under the federal rules." *Id.* at 80

[20] The entirety of Plaintiffs' due process argument focuses on the district court's Rule 702/summary judgment ruling. Plaintiffs do not suggest that there was any due process violation in applying the district court's *preemption* rulings to every action in the MDL. Rightly so: Those rulings were based squarely on legal determinations, apply in the same way to all Plaintiffs, *and no plaintiff suggested otherwise*.

[21] Plaintiffs do not identify the specific individual plaintiffs who fall within this category, nor do they indicate what portion of these Plaintiffs had previously been enrolled in the Registry—and thus bound by the agreement to which Registry claimants subscribed, *see infra* at 97–98 —or were simply cases filed in the first instance after the district court's ruling.

(emphasis omitted); *see Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1330 (11th Cir. 2004).

Plaintiffs' argument concerning the due-process rights of "later-filed Plaintiffs," Omnibus Br. at 1, collapses upon inspection: Plaintiffs insist that these individuals "never had any opportunity to contest general causation with their own experts and record[,]" *id.* at 78, but that is simply not true. To the contrary, *every* plaintiff was given the opportunity to present experts (if they had any), or to show why the district court's rulings on general causation should not warrant summary judgment against them. Plaintiffs failed to do so, and the district court therefore granted summary judgment against every plaintiff.

Even on appeal, Plaintiffs have failed to cite a single instance where *any* plaintiff even attempted to show the district court that it would have been improper to render judgment against that plaintiff. While they complain generally about lack of discovery, they do not identify any information that would have been discovered and not subsumed by extant discovery. Nor have Plaintiffs even specified which action or order violated later-filed plaintiffs' due process rights. The district court's show-cause process was clear from the beginning and fell well within common practice and due process boundaries. The Court should reject Plaintiffs' contention to the contrary.

A. Plaintiffs agreed from the outset that any Rule 702 order would apply to all designated-cancer cases

A review of the MDL pretrial proceedings confirms that, as the district court summarized, "the case management structure of this MDL always provided for the Court's general causation rulings to apply to all of the Plaintiffs' cases[.]" MDL.Dkt.6444 at 8.

Early in the MDL proceedings, the district court identified leadership counsel. In its first pretrial order, MDL.Dkt.13, it provided that Plaintiffs' Steering Committee would "[i]nitiate, coordinate, and conduct all pretrial discovery on behalf of plaintiffs in all actions which are consolidated with the instant multidistrict litigation[,]" "[c]onduct all discovery … on behalf and for the benefit of all plaintiffs[,]" and "[s]ubmit and argue any verbal or written motions presented to the Court on behalf of the PSC[.]" *Id.* at 13–14. The district court explained that leadership counsel's duties included "prosecuting *any and all* potential common benefit claims and class claims, as well as coordinating the pretrial proceedings", "coordinat[ing] the initiation and conduct of discovery on behalf of the Plaintiffs", and "brief[ing] and argu[ing] motions for the Plaintiffs[.]" MDL.Dkt.685 at 13–15 (emphasis added).

The court defined "common benefit" work product as including "all work performed for the benefit of all Plaintiffs and [Registry] Claimants, including pretrial matters, discovery, trial preparation, trial, a potential settlement process, and all

other work that advances this MDL to conclusion." MDL.Dkt.1408 at 4; *see also id.* at 4–5 (applying that order to "all cases now pending in this MDL, as well as any case later filed … and treated as part of the coordinated pretrial proceedings[,]" including all future or pending registry claims). Thus, Plaintiffs' Leadership ultimately made formal submissions about which cancers were to be deemed "Designated"—*i.e.*, for which they would submit expert testimony on behalf of all relevant plaintiffs that the cancer was caused by ranitidine. That slate of experts, tendered on behalf of all Plaintiffs, was the subject of the Brands' Rule 702/summary judgment motions.

The district court also took care to specify the implications of the pretrial proceedings on those claimants participating in the Registry that had not yet filed a complaint. For example, the district court required that Registry claimants sign a consent form confirming:

> a. Each Claimant is bound by the terms of the existing PTOs, consents to the authority of the Court to issue additional PTOs governing Claimants, including but not limited to those furthering the Registry's purpose of assisting parties in the joint investigation and assessment of potential claims, and consents to this Court's jurisdiction as to the operation of the Registry, common benefit funds, and any other dispute related to the operation of any PTO in this MDL or contract related to the Registry.
>
> b. In order to negotiate these PTOs, each Claimant agrees that Lead Counsel is authorized to represent them in these negotiations and, more broadly, to act on their behalf to the same extent as a Filed Plaintiff in this MDL.

Id. at 32.

Further, "[t]he parties designed the Registry to continue in force until shortly after this Court's *Daubert* ruling on general causation." *Id.* at 6. And "[t]he parties agree[d] that the Registry process" was "created with the intent to trigger expiration of the Registry and associated tolling upon entry of an Order ruling upon *Daubert* motions directed to general causation." MDL.Dkt.547 at 12. PTO 72 also set a deadline for registry plaintiffs to certify, before the Rule 702 briefing and rulings, that they would remain within the federal MDL, and would not— presumably due to an adverse ruling on the Rule 702 issues—later seek to add new defendants in an effort to destroy federal diversity jurisdiction and seek remand to state courts. MDL.Dkt.6140 at 14–16.

These pretrial orders reflect the parties' and the district court's intention to have the Rule 702 issues on general causation litigated *once* in a manner fair to all the parties. As the district court later noted: "Plaintiffs conceded on the record that the Court should grant summary judgment for the Defendants if the Court granted all of the Defendants' *Daubert* motions." MDL.Dkt.6120 at 336 n.170 (citing to MDL.Dkt.6242, Sept. 22, 2023 Rule 702 Hearing Tr., at 195–98). Moreover,

> At *no point in time did any party voice an opinion* to the Court that, although the Court should adjudicate general causation as quickly as possible, *the Court would continue to adjudicate general causation on a rolling, case-by-case, individualized basis* so long as additional cases continued to be filed in the MDL.

MDL.Dkt.6444 at 9 (emphasis added).

Accordingly, it is a mischaracterization of the proceedings below to suggest that the only plaintiffs directly involved in the original summary judgment motions were a few "bellwether" plaintiffs. Omnibus Br. at 79. In truth, *every* designated-cancer plaintiff participated, through Leadership Counsel, in the Rule 702 proceedings. As for bellwether trials, the orders were equally clear that the district court would *first* entertain Rule 702 motions to determine which experts were, in fact, eligible to testify about ranitidine's ability to cause the designated cancers. MDL.Dkt.1194 at 1–2. Only *after* that process concluded would the court conduct "the first personal injury bellwether trial in this MDL." MDL.Dkt.4683 at 11; *see also* MDL.Dkt.767 at 2.

B. The district court properly used a show-cause process to grant summary judgment in favor of all Defendants and against all designated-cancer Plaintiffs

After the district court issued its summary judgment ruling, the Retailers and Distributors (and other Defendants) asked the district court to invoke Rule 56(f) (allowing for summary judgment, without a motion, after notice and a reasonable time to respond) to grant summary judgment as to all Defendants in all actions involving designated cancers.[22] In response, and as "the Plaintiffs ... requested,"

[22] At that point, Retailers and Distributors were still before the Court with respect to Count VII, which had not been certified under Rule 54(b), so Rule 56(f) summary judgment could move forward immediately on that single count. With respect to the

MDL.Dkt.6444, the district court instituted a show-cause process under Rule 56(f). MDL.Dkt.6303; MDL.Dkt.6444. *See generally Burton v. City of Belle Glade*, 178 F.3d 1175, 1203 (11th Cir. 1999) (explaining, prior to enactment of Rule 56(f), that a district court may grant summary judgment *sua sponte* after notice to the losing party); *Cafaro v. Zois*, 693 F. App'x 810, 815 (11th Cir. 2023) (citing *Belle Glade* along with Rule 56(f)).

In doing so, the district court was on solid ground, employing a conventional, and entirely appropriate, MDL technique for addressing cases that remain after an issue has been fully and fairly litigated in connection with some other subset of cases. *See Home Depot*, 59 F.4th at 65–66 n.6 (describing use of show-cause process to extend prior MDL rulings to other parties and cases within the MDL).

In *Home Depot*, the Third Circuit explained that courts can and should manage MDLs in a manner that respects the judicial interest in finality of decisions, so long as the court appropriately balances "judicial economy and fairness to litigants[.]" *Id.* at 65. The Third Circuit identified "proper methods of vindicating these values" in the MDL context—one of which is for an MDL court to "rely on its prior decisions as persuasive, and demand good reasons to change its mind" through a show-cause process. *Id.* at 65–66 (collecting MDL cases employing a show cause process);

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rest of the counts, that would have to await a remand from this Court. When that remand came, the district court expanded the scope of its Rule 56(f) orders. MDL.Dkt.6974 at 3–7.

accord Cannon v. Armstrong Containers Inc., 92 F.4th 688, 713 (7th Cir. 2024) (citing *Home Depot*'s approach of "treating prior decisions as persuasive absent a showing of cause why the issue should be revisited," as "safeguard[ing] litigants' procedural interests in being heard"). That is precisely what was done here. [23]

Following the Rule 702/summary judgment rulings, the district court correctly anticipated that the impending expiration of the Registry's tolling period would cause new cases to be filed. MDL.Dkt.6229 at 1. The propriety of extending the causation ruling to later-filed complaints from Registry claimants is unassailable, as they agreed to be bound by the district court's pretrial orders. *See supra* Section III.A. The district court reminded Registry participants of this consent when outlining the procedures for filing future claims after the Rule 702 ruling. MDL.Dkt.6229 at 2.

[23] The district court included non-designated cancers in the show-cause process, even though "[s]oon after lead counsel's decision not to pursue Non-Designated Cancers, almost every Non-Designated Cancer Plaintiff in this MDL dismissed his or her case without prejudice." MDL.Dkt.6766 at 2. The district court nevertheless provided a two-month window for the remaining non-designated cancer plaintiffs to file supporting expert reports after an initial two-month window for deciding whether to pursue their claims; *none* did so. *Id.* at 2–3; MDL.Dkt.6271. For this reason, the district court dismissed these remaining actions with prejudice. MDL.Dkt.6766 at 4–7. Plaintiffs' Omnibus Brief *does not challenge* this decision.

Other MDL courts have similarly employed a show-cause process after reaching a dispositive ruling on a cross-cutting issue,[24] as have courts that have granted summary judgment to a non-movant.[25] And it is well-established that, as a general matter, show-cause orders afford due process. *See generally, e.g., Louisville & Nashville R.R. Co. v. Schmidt*, 177 U.S. 230, 237-39 (1900).

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[24] *See also In re Fosamax (Alendronate Sodium): Prods. Liab. Litig.*, MDL No. 2243, 2014 WL 1266994, at *10 (D.N.J. Mar. 26, 2014) ("[U]tilizing an [order to show cause] to apply a prior legal ruling to other Plaintiffs in an MDL is hardly inappropriate. …. Rather, several MDL courts have used an OTSC to do just that."), *vacated on other grounds sub nom.*, *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 852 F.3d 268 (3d Cir. 2017) (show cause portion not subject to reversal), *vacated and remanded sub nom.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL No. 2226, 2012 WL 3290145, at *1, n.1 (E.D. Ky. Aug. 10, 2012) ("The Show Cause Order … directed all plaintiffs with claims against any Generic Defendant to show cause why those claims should not be dismissed … [on preemption grounds] ….), *aff'd sub nom., In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig. v. Teva Pharm., USA, Inc.*, 756 F.3d 917 (6th Cir. 2014).

[25] *Brikho v. Greeno*, No. 19-10592, 2022 WL 4137810, at *5–6 (E.D. Mich. Sept. 12, 2022) (Because "Fed. R. Civ. P. 56(f) allows this Court to grant summary judgment to a nonmovant, so long as it gives notice and an opportunity to respond before doing so[,] … the Court ordered Plaintiff … to show cause, in writing, why the Court should not grant summary judgment in favor of these newly-named Defendants."); *see also Santos v. Baca*, No. 11-cv-01251, 2019 WL 3046090, at *2 (D. Nev. July 11, 2019) (ordering that "[plaintiff] show cause as to why Burson is not similarly situated to the other defendants who have received judgment in their favor"). This process was used even before the codification of Rule 56(f). *Marion v. City of Corydon, Ind.*, 559 F.3d 700, 704–06 (7th Cir. 2009) (affirming "district court's grant of summary judgment in favor of any and all named defendants" where "the district court granted defendants' motions for summary judgment" and "ordered [plaintiff] to show cause why it should not grant summary judgment in favor of all other defendants").

Plaintiffs' citation to *PPA Products*, Omnibus Br. at 110, is unavailing. There, the court criticized the district court for "fail[ing] to provide the *McGriggs* plaintiffs the individualized consideration to which they were entitled" by dismissing their claims "*sua sponte* instead of in response to a noticed motion." *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1250 (9th Cir. 2006). But here Plaintiffs *did* have an opportunity to respond; there was nothing "*sua sponte*" about the court's rulings.

The decisive point is that, given the opportunity to explain why the district court's summary judgment rulings should not apply in favor of all Defendants to each plaintiff specifically, Plaintiffs offered nothing of substance. Plaintiffs complained vaguely that they had not had the opportunity to take discovery against Generics—and said nothing about the Retailers and Distributors. MDL.Dkt.6540 at 9. Accordingly, the district court held that through the show-cause process it had given "the Plaintiffs the opportunity to explain how non-Brand discovery could have altered the Court's *Daubert* decision, given that so many of the Court's independent reasons had nothing to do with Defendant-specific discovery." MDL.Dkt.6622 at 21.

In fact, the experts evaluated in connection with the Rule 702 briefing had not distinguished between generic or brand ranitidine in asserting their opinions. They had put forward "generic ranitidine evidence in furtherance of their general

causation burden," and their experts relied on it. *Id.* at 16.[26] The district court thus concluded that "Plaintiffs have failed to persuade the Court that there could be any meaningful general causation difference between Brand Defendants' ranitidine and non-Brand Defendants' ranitidine." *Id.* at 20.

As to Plaintiffs' repeated assertions that they had "no opportunity to present another expert" in connection with the show cause process, Omnibus Br. at 79; *see also id.* at 78, 80, 81, that is false, *see, e.g.*, MDL.Dkt.6444 at 8 ("grant[ing] the Plaintiffs the opportunity to address why the Court should not enter summary judgment as to every Designated Cancer personal injury case in the MDL"). The notion that the district court "rejected … out of hand" any such request, Omnibus Br. at 80, is likewise false, for such requests *were never made*: Leadership Counsel tendered no new experts or opinions, and "no individual Plaintiff has filed a response to the Court's order to show cause or requested leave to file a response to the Court's order to show cause" with regard to Designated Cancer cases. MDL.Dkt.6622 at 6.

Indeed, the district court's first show-cause order explained that "[t]he ability of newly-filed Plaintiffs to participate in the Order to Show Cause process extends even to those Plaintiffs who have yet to have their case formally assigned and

[26] This is unsurprising, as the identification of general causation experts' disciplines and specializations was due by June 2, 2021, MDL.Dkt.875, when the Generics were still before the district court (the claims against them were dismissed on June 30, 2021).

consolidated into this MDL." MDL.Dkt.6303 at 20–21. Nevertheless, the district court later issued *another* show-cause order directing plaintiffs

> to address why the Court should not enter summary judgment as to every Designated Cancer personal injury case in the MDL, regardless of the date the case was first filed, including cases filed on or after August 1, 2022, for of [*sic*] all the reasons the Brand Defendants were previously found to be entitled to summary judgment.

MDL.Dkt.6444 at 8. But "no individual Plaintiff [] filed a response to the Court's order to show cause or requested leave to file a response to the Court's order to show cause," and the district court therefore granted summary judgment to every Designated Cancer case filed to that point. MDL.Dkt.6622 at 6.

The district court issued *yet another* show-cause order (PTO 83) applying both to cases filed after May 5, 2023, and to cases remanded from this Court. MDL.Dkt.6642. PTO 83 allowed plaintiffs two weeks from a triggering event (whether from the date of consolidation into the MDL, or remand from this Court), to "show cause why summary judgment should not be entered in their individual cases." *Id.* Plaintiffs do not assert that any plaintiff upon joining the MDL offered a response. Indeed, Plaintiffs do not mention this order at all in their brief.

In short, the district court, at every stage, invited Plaintiffs to present an argument or evidence that might warrant denial of summary judgment. No plaintiff was barred from tendering expert testimony in support of their claim. Plaintiffs simply failed to do so. There was no denial of due process. Accordingly, the district

court's summary judgment rulings provide a further, independent basis on which to affirm the judgments the district court entered in favor of the Retailers and Distributors.

CONCLUSION

The district court's judgments in favor of the Retailers and Distributors should be affirmed.

Dated: July 25, 2024

Respectfully Submitted,

/s/ Robyn S. Maguire

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CERTIFICATE OF COMPLIANCE

I hereby certify that this Brief contains 25,729 words and complies with Fed. R. of App. P. 28(b) and the word limitation in this Court's consolidation and briefing order. This Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2019 14-point Times New Roman font.

/s/ Andrew D. Kaplan
Andrew D. Kaplan

CERTIFICATE OF SERVICE

I hereby certify that on July 25, 2024, an electronic copy of the foregoing was filed with the Clerk for the United States Court of Appeals for the Eleventh Circuit using the CM/ECF system.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished via the CM/ECF system.

/s/ Andrew D. Kaplan
Andrew D. Kaplan

Addendum

List of Retailer, Pharmacy, and Distributor Defendants-Appellees

DISTRIBUTOR DEFENDANTS
Amerisource Health Services, LLC d/b/a American Health Packaging
AmerisourceBergen Corporation (now known as Cencora, Inc.)
Cardinal Health, Inc.
Geri-Care Pharmaceuticals, Corp.
Golden State Medical Supply, Inc.
McKesson Corporation

RETAILER AND PHARMACY DEFENDANTS
Albertsons Companies, Inc. (improperly named as Albertson's Companies, Inc.)
Amazon.com, Inc.
Bob's Discount Pharmacy
BJ's Wholesale Club Holdings, Inc.
Costco Wholesale Corporation
CVS Pharmacy, Inc.
Dollar General Corporation
Dolgencorp, LLC
Dollar Tree Stores, Inc.
Duane Reade, Inc.
Express Scripts, Inc., as the named defendants, and the separate, related Express Scripts pharmacy entities that may have dispensed brand or generic ranitidine
Family Dollar, Inc.
Family Dollar Services, LLC f/k/a Family Dollar Services, Inc.
Fred Meyer Stores, Inc.
Giant Eagle, Inc.
H-E-B LP f/k/a HEB Grocery Company
Humana Pharmacy, Inc. (improperly named as Humana Pharmacy Solutions, Inc.)
Hy-Vee, Inc.
Innovis Health, LLC dba Essentia Health West (improperly named as Essentia Health)
Kaiser Permanente International
Martin's Super Markets, L.L.C.
Memorial Hospital at Gulfport Foundations, Inc. (improperly named as Memorial Outpatient Pharmacy)

RETAILER AND PHARMACY DEFENDANTS
OptumRX, Inc.
Price Chopper Operating Co., Inc.
Publix Super Markets, Inc. (improperly named as Publix Supermarkets, Inc.)
Safeway Inc. (improperly named as Safeway, Inc.)
Sam's West, Inc.
ShopRite Supermarkets, Inc. (improperly named as Shop-Rite Supermarkets, Inc.)
Smith's Food & Drug Centers, Inc. (improperly named as Smith's Food and Drug Centers, Inc.)
Southeastern Grocers, Inc. (improperly named as Southeastern Grocers, Inc. f/k/a Southeastern Grocers, LLC)
SpartanNash Company
The GIANT Company, LLC f/k/a Giant Food Stores, LLC
The Kroger Co.
Target Corporation
Vitamin Shoppe Industries LLC f/k/a Vitamin Shoppe Industries, Inc.
The Vons Companies, Inc.
Wakefern Food Corporation
Walgreens Boots Alliance, Inc.
Walgreen Co.
Walmart, Inc.
Winn-Dixie Stores, Inc. (improperly named as Winn Dixie Stores, Inc.)